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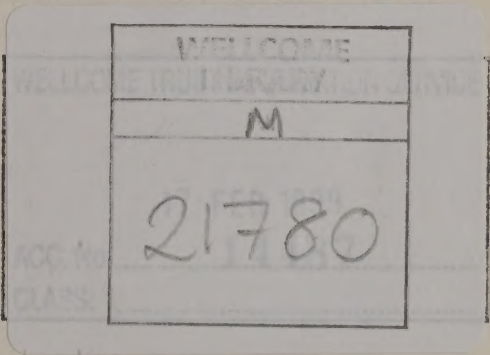
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SELECT COMMITTEE ON
THE EUROPEAN COMMUNITIES

EC REGULATION OF GENETIC
MODIFICATION IN AGRICULTURE

EVIDENCE



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MINUTES OF EVIDENCE

TAKEN BEFORE THE EUROPEAN COMMUNITIES COMMITTEE (SUB-COMMITTEE D)

WEDNESDAY 13 MAY 1998

Present:

Gallacher, L.
Gisborough, L.
Grantchester, L.
Jopling, L.
Moran, L.

Rathcavan, L.
Reay, L. (Chairman)
Redesdale, L.
Wade of Chorlton, L.
Willoughby de Broke, L.

Examination of witnesses

PROFESSOR JOHN BERINGER, Dean of Science, University of Bristol and Chairman of the Advisory Committee on Releases into the Environment, called in and examined.

Chairman

1. Good morning, Professor Beringer. Thank you very much for coming to give evidence to us. As this is the first public session of this enquiry I should like to precede my remarks on the subject by declaring a farming interest, largely as a grassland farmer, but I might conceivably one day have an interest in genetically modified crops although I am not aware of it today. Could I perhaps ask you, Professor Beringer, to introduce yourself and explain the role that you play in the regulation of genetic modification in agriculture

(*Professor Beringer*) Good morning, my Lord Chairman. I am the Dean of Science at the University of Bristol. I have been Chairman of the Advisory Committee on Releases into the Environment and the Committees that preceded it for about 11 years now. My involvement in this area started about 15 years ago, when I tried to interest the Ministry of Agriculture in setting up some form of system to look at the release of genetically modified organisms; so I have been involved right from the very beginning before things were even released. I have also worked during this time, on a consultancy basis and otherwise, with the European Commission, the OECD, the UN, the USDA and various countries around the world in developing thoughts about regulations and guidelines. My actual role, I believe, is to ensure that the best quality advice is provided to make assessments of the risks of releasing genetically modified organisms; and also that the Department of the Environment, Transport and the Regions provides good quality advice and guidelines to people who wish to make releases, so they prepare what they are going to do sensibly.

Chairman] Thank you. Lord Gallacher.

Lord Gallacher

2. Professor Beringer, the Sub-Committee was told that no field trial experiment notification has ever been turned down. Could you explain the procedure which ensures minimal risk, but which appears to accept every application to release a modified crop.

A. We assess the probability that harm will arise from a release. Always you can control the harm that will arise by the way you manage a release. If you fence an animal in you can prevent it straying. If you stop crops from forming flowers they cannot transfer

pollen to other crops. So the basic system is to look at the possible harm that could arise from a release; to look at the way it is being managed to ensure that harm does not occur. If it does not look as if it will be safe, we ask for more information or a strengthening of the management. If we were to believe that someone was not competent to manage the risk, then we would certainly prevent it happening. There have been two cases where we have not given approval. One was for a non-indigenous insect and the other was for a genetically modified insect, where we just did not see that the applicant was going to be able to overcome the problems.

Lord Moran

3. Are the possible risks that you referred to in the public domain? Are they known?

A. The possible risks would not be in detail in the public domain. What happens is that the application to make a release is in the public domain. If you ferret around hard enough you will find all of these. What you will not find is our full discussion where we try to draw out of the application from our own experience, what we believe the true risks are, relative to those that are proposed. There is no mechanism for all of that discussion to be in the public domain.

Lord Rathcavan

4. How do you physically manage and control these risks, Professor Beringer? What staff do you have available and how often do they carry out site visits?

A. The situation is that the Health and Safety Executive takes the responsibility for the Department. It has inspectors who visit sites to ensure that experiments are conducted as they should be. Not all sites are visited in one year. The tendency is to ensure that people who are doing something new, or are new to us, are visited to ensure that they are competent. I have to say that of all the releases we have approved to date, there are none for which there has been any form of serious concern for environmental harm. So there has not had to be very intensive supervision to make sure that serious damage would not occur. It is conceivable that crops will be made in the future to

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PROFESSOR JOHN BERINGER

[Continued]

[Lord Rathcavan *Contd*]

carry genes that produce pharmaceutically active products, which would be a great value in medicine but which must definitely not enter the food chain. We would then be much more in a position of requiring a very efficient system to ensure that those were managed properly, but we have not had that need to date.

Lord Willoughby de Broke

5. There was a report in last week's *Guardian*—this is not field trial experiments, I agree—but about a large-scale organic vegetable grower who was concerned that the pollen from close-by genetically modified maize may contaminate his own crops. Do you have a view on the risk of that? Is that a real risk which should be properly quantified and growers warned about, or is that a newspaper scare story?

A. It is a very interesting story, if it is the same one as I know about which is in Devon, where the organic farm is about 500 metres from a variety trial for seed registration.

6. That is right.

A. My feeling about this is that what we are going to be looking at here is a very, very low frequency with which pollen from the genetically modified maize will enter the organic maize. This means that a few kernels out of all the cobs produced may contain the gene from the genetically modified maize. The situation is that the kernel you actually eat is produced by the plant growing in the field. It does not contain any of the gene products from the pollen which has come from the genetically modified maize.¹ So all that can be consumed is derived from the original parent but will have an extra gene that it did not have before. Therefore, the risks of any harm to people are absolutely negligible. I recognise that there are concerns that if people are growing organically, so-called pure food, they do not want it to be contaminated with something they do not like. Of course, the situation is that anyone growing maize, genetically modified or not, that maize is transferring genes which are not in the organic maize, so it is always contaminated by any adjacent maize. It is the nature of the gene that is derived from the genetically modified product, which is the cause of the problem, but as far as I am concerned is not a cause for harm.

Lord Jopling

7. Before I begin I should, like the Chairman, declare an interest as a farmer. I am also a member of the National Farmers' Union. You gave us two examples of where applications have been turned down, and you gave us one hypothetical example where in the future you could foresee an application being turned down. Could you speculate a little further and tell us what are the general headings of where you could imagine there being reservations about either of those applications which are now in the pipeline, or

applications which may come in the future which would cause that application to be turned down. I am thinking of a similar one to the pharmaceutical one which you mentioned earlier.

A. I did not say that the pharmaceutical one would be turned down. I said that I thought this is a development which could be very valuable but these crops would have to be kept very separate from the food chain. What we would wish to turn down would be the introduction of, let us say, the introduction of peanut protein gene into wheat or some other crop that could enter the food chain, and people would eat food then with a very well-known, very serious allergen. I can find no possible excuse for wanting to make a release of that nature. However, if there was some scientific reason why that needed to be done for a proper understanding of science, I think we could come to an agreement with a very high degree of very stringent management so that this could be accepted. But it would be very, very hard to approve. We are going to have difficulties in terms of what is coming with crops such as frost tolerant potatoes, where these potatoes will become a greater problem in following crops than potatoes already are. After a mild winter, existing potato crops can cause severe weed problems in following crops. It is usually frost that controls the problem. So I can see this will be a difficulty but I think the agronomic benefits will be higher than the agronomic disadvantages of increased weediness. We would need to work that one through and understand properly what might be other environmental implications. It is very difficult, as you are seeing, to identify things that we could not possibly allow.

Lord Gisborough

8. Could you say to what extent (if at all) diesel rape could cross-fertilise with the edible rape as one is inedible.

A. That very much depends on which way the bees are flying; how much pollen is available and how close the adjacent crop is. The frequency of cross-pollination could be really quite high. If you were saving seed and resowing it, you would have a significant proportion—maybe 10 per cent at a high level—in your following crop. In order to give approval for any genetically modified crop to produce higher levels of oil that could be used as a diesel substitute, that would have to be taken into consideration. But the oil which is produced from rape to use as a diesel substitute is oil that we eat anyway so it is not a nutritional threat.

Lord Jopling

9. Professor Beringer, ACRE tells us that it works on a precautionary basis, by giving advice to Ministers on the conditions which should be attached to a consent. Could you tell us what ACRE does to ensure that those lessons which are learnt from field trials, are used by ACRE and other bodies in assessing further implications from either the same applicant, as an earlier one, or new applicants.

A. Yes, of course, I can. However, I think the difficulty in answer to this question is that nearly all

¹ Professor Beringer qualifies this by adding that the embryo and the endosperm will contain some products made by genes derived from the male parent.

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PROFESSOR JOHN BERINGER

[Continued]

[Lord Jopling *Contd*]

the field trials which have been done to date have been so highly managed to reduce any chance of any harm, or any risk of harm, that we cannot really learn anything from them because we made sure that there was nothing that could happen which was unexpected. Having said that, we have experienced from trials that were done specifically to look at frequencies of gene transfer, which have been very valuable to us in determining probability of gene transfer, and which have basically told us that we must assume that genes will be transferred to other potentially cross-pollinating varieties of the same crops and sometimes weeds. The distance can be up to maybe a couple of miles at very low frequency. It is worth remembering, of course, that a genetically modified organism is the existing crop plus one or two extra genes, so we still get plenty of information from our knowledge of existing crops. What does wheat normally do as a weed with the few hundred thousand genes that it already has? Also, we are now learning from experience in China and North America, where these crops have been grown in millions of hectares. If anything unexpected is going to happen, they are going to give us advanced warning long before in Europe, at the present time, we are likely to see anything.

Lord Grantchester

10. Once these genetically modified foods are grown, do they act very similarly to hybrids, either in that they do not breed true, or at all? That they do escape into the wild, but that the properties they are given to grow in a specific crop do not lock into that variety for the future.

A. The genetically engineered crop is no different, in terms of whether it breeds true or not, to the same crop grown otherwise in agriculture. So if it is an F1 hybrid it will not breed true. If it is not an F1 hybrid or is self-pollinating it will be relatively true breeding. If it is cross-pollinating it will not. These are not different conceptually, or in terms of their make-up, than any other plant. They just happen to have one or two more genes in their chromosomes, which segregate and cross as any other genes. They are not unnatural in that respect.

Lord Wade of Chorlton

11. First, I must also declare an interest as being a farmer and also a director of a company that is an international trader in milk products, fish and meat products; not grain products, I should mention. My question relates to cross-border activities. Does ACRE take into account information about field trials undertaken elsewhere in the world? What information is required from the applicant about field trials in other countries? Are dossiers prepared by the applicants, (for example, in Ireland), acceptable in the United Kingdom?

A. We do not have, as a requirement, that field trial results in other countries are part of the application, although if there was relevant information from elsewhere it would be a requirement if that

information affected the risk assessment. I should point out that the consent that is issued from the Department is a consent that says: "If any new information comes forward, it is your responsibility to make that known if it affects the risk assessment." So any consent is entirely limited by any knowledge that comes from anywhere and it could be abroad. You ask the question as to whether we can accept a document presented within another country. Yes, we could. In reality the difficulty is that we have a very set series of questions that we like answered, and if you have a dossier for another country it may be that one or two of those are not answered. So very often I think people would tend to dress up their existing dossier for another country to make sure they answered our questions. But, in principle, yes, we could. In practice it actually would be probably more difficult because it would require a number of returns to get all the questions appropriately answered.

Lord Rathcavan

12. My Lord Chairman, I should declare an interest as a small hill farmer. Professor Beringer, I think you have probably answered the gist of this question. It relates to the call by English Nature for a three-year moratorium. Perhaps you would like to respond to what English Nature has said and whether you feel the risk assessments are adequate.

A. I think I am bound to say that the risk assessments are adequate, since I chair the Committee that makes these risk assessments! You would be surprised if I said otherwise. I do not believe that a moratorium would be helpful because I have not seen harm defined in terms of anything that we are looking at, at the moment, which would make me feel that we should not proceed because harm will be caused. I have heard plenty of concerns about lack of knowledge, lack of predictability, but those concerns are not different to me than the same concern with a traditionally bred crop which may have been crossed with a wild weedy relative with many unknown properties. So I do not see that what we are looking at, at the present time, as being significantly different. I do not think we would learn from a moratorium and I do not think a request for a moratorium properly understands that this is not a totally new technology which is untested. We must remember to look at the United States, China, and elsewhere, where we now have millions of hectares of crops that are not mystically killing birds (or whatever) through totally unknown processes as a result of the technology.

Lord Willoughby de Broke

13. I have an interest to declare as an owner of a mixed farm in Warwickshire, arable and grassland. I am also chairman of a publishing company that publishes a country interest magazine, *Country Illustrated*, which would be very interested in writing something on this subject. As to my question: we are aware that in the interests of transparency, ACRE publishes grid references for each experimental release. We are also aware that this information is

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PROFESSOR JOHN BERINGER

[Continued]

[Lord Willoughby de Broke *Contd*]

compiled on Internet by those who would advocate the destruction of such research sites, and that this destruction is taking place. How do you propose to counter this and can it be countered?

A. We have discussed this issue. We do not propose to counter it. We think communication is extremely important. We think it would be an extremely retrograde step to withdraw knowledge of where this work is being done. Having said that, I should make the point that the reference is to the farm that is growing the crop; not where within that farm, the specific point where the trial is going to be. We do offer advice and we have actually told people not to put fences up around their genetically modified plots. We think that a lot could be done by the people themselves so that these trial plots are not too obvious. I have to say, of course, that we are now looking at much larger areas for seed multiplication and things of this nature, where it just would not be feasible for vandals to destroy the whole of the crop. My belief is that this is a brief phase, as has happened elsewhere, and that it will soon die down to be relatively inconsequential. I hope it is. If it is not and if it gets a lot worse we will have to reconsider, but I would be very sorry if we were moving to a position where we no longer gave information that is helpful to people.

14. Those who would advocate destruction, are these individuals or are they organisations, as far as you know, who feel that what you are doing is wrong?

A. I think it is both. There are some individuals who feel very, very strongly that you should not interfere with nature, forgetting that most of our food is interference with nature, but that is another matter. I do believe there are some organisations who are strongly opposed and are trying to increase awareness. I would not like to say who is responsible for any of these because I do not know.

Lord Grantchester

15. How many occurrences have there been?

A. We are probably up to our fourth or fifth now.

Lord Gisborough

16. I should declare an interest as an arable and sheep farmer. Directive 90/220 applies in all countries in Europe. Is the assessment of projects similar in all the different countries, especially where very nearly the same organism is to be released under similar conditions?

A. The best answer I can give you is that similar is a word which allows great discrepancy in action. This is roughly what is happening. There are different interpretations within the Member States as to what is harm, and as to what information is needed. Basically I believe that all the assessments have a level, which is not lowered, that ensures safety. There are certain things: for example, the French are extremely keen to know about the sequences of genes that have been inserted in bits of DNA. We have yet to identify how a sequence tells you anything about potential for environmental harm and are not so concerned. Some

countries are worried about the expressions of the genes; how much they are expressed. We believe that gene expression varies through environmental changes. Therefore, it is wrong to put too much emphasis on having gene expression because it may be quite different, so you should assume differences. We are all working to the same sort of objective; the similarity is relevant here as being something that is not absolute.

Lord Moran

17. Can I declare an interest? My wife has a very small herd of pedigree Welsh black cattle on a hill farm in Wales. We are not yet into genetic modification. If I may, could I go back to question 4 on environmental risk assessment? You yourself were quoted in *The Daily Telegraph* on 25 March as raising concerns, on behalf of your Committee, about the introduction from next year of crops which tolerate herbicides, which would remove what few food plants remain in today's arable fields for birds and other wildlife and therefore have a fairly dramatic effect on them. I wondered if you still have those concerns and whether you thought there was anything effective that could be done about them. This is because obviously if it does spread on a big scale it will have a serious effect on species that are already in fairly dramatic decline.

A. Thank you for that question. I must state that I very seldom, if ever, speak for the Advisory Committee because I would not trust myself to reflect what they believe. This is a concern of mine which I do not see as a specific concern relating to the release of a GM plant. If you do not use a herbicide on that plant it does not matter whether it is genetically modified or not. There will be no effect on the weeds. We do approve the use of herbicides in agriculture. It is fairly clear that herbicide tolerant crops will improve the efficiency with which weeds are killed. The more efficiently you kill weeds the less food there is for wild animals. That is quite clear. That is simply making worse an existing situation which is totally independent of genetic modification. Genetic modification is simply allowing a system that is not quite as efficient as it could be, to be more efficient, so it is not unique and special to this. I believe this is an important issue because also we will be seeing crops that are resistant to attack by insects. If these become very widespread there will undoubtedly be fewer insects in the environment and, therefore, less food for birds. So there is the potential for a further decline in bird populations. On the other hand, it may be that by removing the need for pesticide use there are more insects from hedgerows and adjacent areas, so there might be more food for birds but we are not sure. These are very much secondary issues. These are not issues for ACRE, which is a committee that looks at the safety of the genetically modified crop. My concern is that there is a vacuum in the political system, which is not looking at how changes in agricultural practice are linked to changes in the environment we see. I think we all must remember that the environment we see and like is that environment

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PROFESSOR JOHN BERINGER

[Continued]

[Lord Moran *Contd*]

which farmers produce for us. If we want it to stay as it is they have to do what they are doing now, pretty roughly, which is not what nature would intend. Somehow or another, the debate is how we are going to have what we want, which is artificial, and handle change which must happen. However, it is not one I believe that a committee, which is trying to ensure safety, should be actively involved with, because it will divert us from our major role.

Lord Moran] Thank you very much. That was very interesting.

Chairman

18. Could I come back to the question of other Member States. Is there any liaison between ACRE and your counterparts in other European countries on applications? To what extent are you advised about applications in other countries and any reservations that may be made by those authorities about the releases they authorise?

A. Not all countries have advisory committees. It is worth pointing out that the regulatory system requires that each country has what is called a Competent Authority. These are the civil servants with responsibility for ensuring that the legislation is properly carried out and safely. We do not really, as an advisory committee, see very much relating to trials in other countries. It is probably just as well because they would not be terribly relevant to our environment and the way we are doing things here. We do see all the marketing applications and we comment on those. The competent authority, on the other hand, is aware of what is going on elsewhere and does sometimes come to us for advice, but we have no role as to whether another country may make a trial release or not. I think that is entirely appropriate. I do not think we would learn from these other trials because, as I said earlier, they tend to be so small that there is little you can learn from them. The last thing we should ever do is to say no harm occurred in that trial. If that trial is too small it tells you nothing about the harm which may occur with a very, very big one. So for very small trials which are very heavily managed, we need to be careful not to assume we can learn too much and use it too far.

Lord Gisborough

19. Should there not be an international control of some sort? Was not the release of the bee from Indonesia a prime example of bees throughout the world being put in jeopardy by the release of the grower?

A. Regrettably, as you have just said, no matter what regulations you have people will do stupid things. Somebody took bees up into Scotland recently and moved further north varroa mites by one hundred miles or so through crass stupidity. We will never overcome that. I do think it is extremely important that we rapidly understand that there is a world beyond Europe, and that in much of the world genetically modified crops are being deregulated. By

definition, therefore, they are not subject to careful constraint. By definition, therefore, bulk commodities will be contaminated with genetically modified seeds, whether we want it in Europe or not. I have argued for at least five years with the European Commission that they really had to think what was going to happen. That commodities were commodities and they had to start believing that there was a world out there. That the Americans were not perverse and stupid and that things would start to come. We have not properly grasped that nettle and done something about it. I think it is critical to the development of agriculture in future, the movement of food in future, world trade, and common sense.

Chairman] This leads on to the question, Lord Moran, you were going to ask on that.

Lord Moran

20. The Committee has been told that very few applications for the commercial use of GM crops in agriculture have been approved in Europe. The process can take a long time even though there are very strict time limits on consideration by the country in which the application is first made and on subsequent consideration by the other 14 Member States. Can you tell us what the problem is and hopefully how the situation could be improved.

A. I am not sure what the problem is because I am not all wise. I think it is fairly clear from discussions with industry and American colleagues that it is the regulatory environment in Europe which is a major stumbling block. I believe the main reason for this is that the regulatory process here is derived on the basis that if you are genetically modified you must be subject to regulation, the implication being that genetic modification inherently makes something potentially unsafe and therefore requiring a strict regulation. Whereas in North America, particularly in the United States, the decision was made: "We must use existing product legislation because what we are interested in is whether or not this new product is safe. If it is safe then fine, it does not matter how it is made, it is irrelevant, it is safety which is important." I think the big problem we have here in Europe is that we still do not properly understand that what we need is to determine the safety of what we are doing. We are getting major delays in the system because there are concerns about whether or not we should be using the technology; the socio-economic issues that may or may not be involved; and a very weak, ineffectual and (I would even use the word) incompetent system in Brussels, which is allowing various delaying tactics to be introduced, which is making marketing so very slow. If I were an American I would not begin to think of marketing in Europe until this was tidied up. I think it is a serious impediment for us. It is a serious impediment for European industry. It is something we have to try and resolve. But it goes back to something I said earlier, which is this gap we have in terms of agricultural policy and the environment. At the moment, Directive 90/220 provides an opportunity for people who want to look

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PROFESSOR JOHN BERINGER

[Continued]

[Lord Moran *Contd*]

at socio-economic issues to do something about it. I believe that is wrong because I do not see them as safety issues, but I do see them as very important issues.

Lord Jopling

21. Some people think the Americans much too lax, free and easy in giving consents. Is that your feeling?

A. No, it is not my feeling. I know the people very well. I actually think that they have been more critical and more careful than the great majority of them would choose to be, because they have sat down and looked very carefully and asked the question: "If I put this gene into the crop what is the potential for harm?" If they have not been able to identify harm then they have decided that releases should proceed. We are still on the basis of saying that if we do something new, what are the unexpected things that might happen that we cannot predict? We assume that a genetically modified plant is unique in our inability to predict what could happen. However, all of you who have anything to do with farming will know that a new variety of any crop coming on the market is unpredictable. You get a different season and suddenly it does not do what you predicted. There is nothing new here. Somehow in Europe we have not grasped that. We still think that if you cannot say that a genetically modified thing is totally predictable, it is therefore unsafe and different.

Lord Grantchester

22. Taking up that point as well, Professor Beringer, about safety, can it be compared at all historically to the United States' practice over drugs safety? Several times within my experience in agriculture, when talking to vets, they say: "You can get such and such product if you are in America but not here. It is relatively untried and untested, rather risky, and it is not licensed in this country." Is it a similar situation with the licensing of genetically modified food?

A. I have to say that I am not competent to judge in terms of drugs safety. What does interest me enormously is that the United States is notorious for litigation. We somehow talk about the Americans agreeing to do things that are unsafe as though they did not care about the consequences. In fact, the likelihood of an American company ending up with abnormally high legal costs and fines or whatever, through the result of doing something wrong, is enormously greater the other side of the Atlantic than here. I do not believe this often stated comment, that they do not take as much care as we do. They may do things differently but that does not make them unsafe. It does not make us more safe or less safe. For each and every product there will be differences. Sometimes they will be more careful and sometimes we will be. That will reflect the expertise which was available for those risk assessments. That is inevitable.

Chairman

23. Do I take it from what you say that you, therefore, would not be in favour of developing more elaborate monitoring arrangements in Europe?

A. You are entirely right. I think the suggestion in the modification to Directive 90/220, that there will be a seven-year monitoring period, is absurd. I do not think it will add at all to safety. I do not see how it can be done. I can see it will offer immense opportunities for critics of the technology to say that monitoring has not been done adequately. For the people who sell seed for them to say: "But we could not monitor because to monitor everything properly anyone might want us to monitor is too large a job. Therefore, we can never deliver." So I think this is simply going to set up another point in the system over which there will be endless controversy.

Lord Wade of Chorlton

24. May I follow up that argument a little bit. I agree entirely with your view that we have come at this thing the wrong way round in Europe and assumed that there is something inherently wrong with interfering, but we have been interfering, as you so rightly said earlier, with nature and the development of plants and breeding techniques ever since time began. None of us would have survived this long if we had not done it. Why do you think it is that there is this concern about the process rather than the result in Europe? Where did we—probably not at the very beginning—present gene technology in the way that showed it in the more positive light? Why do we have these concerns and what can we do to address them more effectively?

A. My own belief is that it goes right back to the very beginning of this technology when the scientists concerned at the Asolomar Conference said: "We believe there are risks which at the present time we cannot determine. Therefore, there should be a moratorium." The way we resolved that was to say that genetic modification would be done under containment similar to that of comparable pathogens that would be handled in a hospital. For release it has always been the problem, in my mind, that what we are now saying to people is: "Not only does it no longer have to be handled in a laboratory, but you must put it in your mouth." Many people are now saying: "I do not want to put it into my mouth. I do not know whether it is genetically modified or not, so I do not even have that choice." So I think we have gone through an enormous change and I do not think it is at all simple. Within Europe also we have the problem that we are not so keen on new technologies as the Americans, so it has been harder. There are not as many hungry people as in China so there has not been the incentive to develop the technology further. I do believe, as I will say again, that there has been this gap. We are all worried about what is going to happen to the environment. What is our agriculture going to do in the future? We see this, many of us, as another turn

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[Continued]

[Lord Wade of Chorlton Contd]

of the screw that may alter the environment around us in ways that we do not desire. We do not see any way in which these can be articulated and carried forward in any planning in the country. Those, as I say, are entirely personal views.

Lord Redesdale

25. Following up on that point, to what extent, if a gene which had harmful effects did start to be pollinated throughout other crops, how easy would it be then to control the spread of that?

A. If it was a gene that is, let us say, for frost tolerance, that escaped to oil seed rape, which would not be needed, (I am trying to think of one I can answer simply), that could get into related weeds and if it conferred a selective advantage it would remain in those populations.

26. So it would be almost impossible to eradicate?

A. Exactly. Although that would be exactly the same as any gene that comes in, at the moment, from wild weedy relatives through normal breeding, which are also entering the gene pool of our native varieties which cross-pollinate these crops.

Lord Grantchester

27. I declare an interest as a dairy farmer in Cheshire. I do not know whether there is any genetic modification in dairy farming, although I understand that a good deal of gene mapping is going on for inheritance purposes. No doubt changes in the characteristics of milk may well soon be on the horizon. An application could be made to any of the competent authorities of any Member State in which an organism is to be released. Are you aware of the reasons for the choice of a particular country?

A. The choice is meant to be the country in which one expects to have a major proportion of one's sales. I have experience of only one case where I believe a company, Plant Genetics Systems, came here as a result of discussion. Patrick Rudelsheim, its regulatory affairs director, and I attended an international conference where there was discussion as to where PGS might go with its application for oilseed rape. I believe that I managed to convince him at that time that our Competent Authority here was excellent. I believe that PGS came here with its application partly as a result of that. I do not know why people go to other countries, although I am pretty sure that there are some countries that are not attractive because one would not expect the system to be as efficient as others.

Lord Wade of Chorlton

28. I want to ask about the bulk shipment of crops. Genetically modified products deregulated in the USA and Canada are now part of bulk shipments of commodity crops about to be imported into Europe. Many of these will not have received European regulatory approval for environmental

release or for food use. Is this a cause for concern? Do you see this as a factor that is likely to decrease public acceptance of the technology?

A. I do not see it as a cause for concern from the point of view of safety but it is a potential problem from the point of view of public acceptance because it exacerbates the difficulty that some people have. They want to know whether or not their food may contain some component that is derived from a genetically engineered plant. The difficulty is that this situation can only get worse. At the moment in a number of countries farmers are growing genetically modified crops from seed that they have personally moved across borders. It will therefore not be possible even if one obtains grains from Brazil or Argentina—to pick two large countries - to be absolutely certain that none of it is contaminated. We have to get down to the nitty-gritty of this and point out the dilution factor and absolute safety of what is happening. If we lose this debate and public confidence in the safety of food—it is safety that is important, not emotion - we will be in a serious situation. Emotion will override international trade. It will result in enormous complications in terms of the movement of food. If we ban all imports from America and any country in which there is any possibility that a genetically modified crop is grown we will have food shortages. That is a terribly serious issue that I do not believe has been tackled.

Chairman

29. Does that mean you do not believe in the long-term feasibility of segregation, although some retailers believe that that should be possible?

A. I regret to say that I have a greater belief in human nature. If there is a niche market to be obtained by selling something that is not genetically modified I am quite certain that a number of people will ensure that their material carries that label.

Lord Jopling

30. We have been provided with the notes on the recent Agra-Europe Conference in Brussels on this issue. I note that a Mr Thorne¹ from the United States Department of Agriculture states: "Segregation on a large-scale basis is flat out impossible." Yet a little later in the same document one sees the comment by a Mr Wadsworth,² technical manager of Iceland Frozen Foods, that recently his company had "negotiated the supply of GM-free soya beans from Canada and Brazil but care had to be taken to ensure continuing segregation during transport." While it may not be your field, my guess is that it is absolute nonsense to say that segregation cannot physically be achieved. After all, it is well known in the field of malting barley and hard wheats where there is a very clear definition of quality wheats which command various prices from North America. I cannot for a moment see why it is not possible to

¹ See oral evidence of 8 July.

² See oral evidence of 10 June.

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[Continued]

[Lord Jopling *Contd*]

segregate genetically modified grains when the material can be analysed to see whether or not it has been genetically modified?

A. I accept what you say for small quantities. Iceland somewhat overrates itself if it believes that it is a major player in the world movement of cereals. If one wants complete segregation of major commodities such as soya bean or maize it will cost billions of dollars. It could be done. On the other hand, if one is a small niche marketer one can always expect people to segregate on a small scale and pay a premium for that. I have no problem with that. If one knows anything about malting barley one knows that primarily it is the nitrogen content that is important. It is not a bad thing to dilute it if you have very low nitrogen and some high nitrogen to boost up the value of the high nitrogen crop. I am quite sure that equivalent things will happen with commodity cereals because that is human nature. My point is an absolutist one. It will not be possible to say that there is absolutely no contamination unless one is a small importer with extremely high controls.

Lord Jopling] For the record, I notice that in the same extract Iceland talk about 60,000 tonnes of soya bean shipments a month. That is not huge on the world scale but it is significant.

Lord Wade of Chorlton

31. I agree that these materials can be segregated, but given the world trade movement of such products and the enormous increase in their production in the United States, the main producers and also China and other parts of the world, the cost of segregation could be enormous. As the expert on these matters, you have made clear that at the end of the day both products are perfectly safe to eat. The perception is an emotional one; it is based on bias and prejudice and not fact. Would it not be more sensible from the point of view of world trade and world food needs to spend the money on teaching people about the value of these new products rather than spend the money segregating products which there is ultimately no need to segregate?

A. My biggest concern is that the great majority of people in this country have absolutely no interest in what we are talking about today. They are interested in not spending too much money in supermarkets on food. I would be deeply distressed if we designed a system which forced through a United Kingdom requirement for specially segregated crops which would undoubtedly cost more as commodities and raise the price of food, because a small minority of very articulate people had pushed it through. I am entirely happy that there is a niche market for labelled materials that are not genetically modified, but I think that it would be totally wrong for the general public to pay more for food because

of an issue that has nothing whatever to do with safety.

Lord Grantchester

32. Therefore, do you see the labelling of food as containing genetically modified organisms as fundamentally misconceived? Do you say that in any event food must be safe and therefore the labelling would apply only to the niche market that you have identified?

A. I look upon the issue of labelling as an emotional and political matter. I do not see a safety problem which requires that there be a label to say that certain food may contain say one per cent of a genetically modified crop. I see it as a very important issue in terms of people who look at food as something that should be natural and therefore want something that is not genetically modified. I am strongly against the labelling of bulk commodity foods for the sake of it. I am very much for the labelling of material that has not been genetically modified, if that is what people really want.

Lord Redesdale

33. Should regulatory approval in one country automatically apply worldwide? How would it be possible to police a system where deregulation in one country had made the growers, producers and exporters unaware of its status in another country?

A. I am afraid that my interactions with the United States and EU trying to talk to each other has made me feel very leery about saying that there should be international approval of each other's agreements. That is a sensible way forward. It is probably the only way forward looking ahead 25 years, but at the moment it is not reasonable to expect that we can do that. I am actively involved in helping to draw up international procedures and such like. The advisory committee was involved in international guidelines on biotechnology. We are concerned to try to find ways in which things can move around so that countries know what is happening. It is a long step from that for us to agree Chinese, American, Portuguese, Greek or whatever risk assessments without any second thoughts. But it must happen because this technology will not go away; it will be pervasive. In many, many countries it will be accepted as an entirely normal plant-breeding process. We are not going to live in a vacuum; or if we are we will find it very strange and difficult.

Chairman] That is a very good note on which to end your evidence. Thank you very much for your valuable and authoritative comments. It was a fascinating combination of comment and facts and will repay thorough study when we see the transcript. I have received a request for you to stay for the first of the questions to be put to Professor Burke.

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[Continued]

Memorandum by Professor Derek Burke former Vice-Chancellor, University of East Anglia and former Chairman of the Advisory Committee on Novel Foods and Processes (ACNFP)

(A paper delivered to the 1998 annual conference of the National Farmers' Union of England and Wales)

1. Courtesies.

2. Over the last year, genetically modified foods have been entering supermarkets in Britain. The outcome has been mixed; for some have been accepted without hesitation by the public; for example, "vegetarian cheese" and the paste made from genetically modified tomatoes. But others, notably the flour from genetically modified soya beans and an insect resistant corn have caused considerable controversy. Why is this, and what will be the effect on the farmer?

3. I do not need to remind you how much change your industry is going through. First, there have been massive changes in the agrifood business, with substantial consolidation so that only a handful of companies are left, all operating world-wide. The seed companies have also been caught up in this rationalisation, as have the plant biotechnology companies. Then too, major changes have taken place in the food industry over the last 20-30 years, in particular in the role of the big supermarket retailers. The food retailers, with their formidable buying power, control the food chain. The consumer now expects a very wide choice of foods at ever decreasing prices and constantly improving quality. Then there is a third agent for change, for the development of biotechnology can provide products which are cheaper, healthier or last longer.

4. Biotechnology depends on our capacity to move any gene from one species to another, and to get it to work in the new host. The old species barriers have gone. So materials made by humans can now be made in bacteria, and substances made by bacteria plants. Some of the applications of biotechnology are obvious; the supply of insulin for diabetics is no longer limited. Farmers will be able to use less herbicide in raising crops such as soya, and lose less of their corn crop to insects. Recently too, other genes, genes that control plant development have been isolated: for example, the genes that control flower shape and colour in the snap-dragon so that we can start to manipulate flower shape, and control colour for the horticultural industry. More importantly, the genes that control the plant's response to day length have been isolated, so that it may be possible, by modifying these genes, to produce plants that come to maturity more quickly, with a huge economic impact.

5. What is Biotechnology likely to produce? It offers the food industry new processes and new products. The most straightforward developments will be a whole series of new and improved enzymes for food processing, for example, the enzyme chymosin used in cheese curing and now largely made in bacteria. Biotechnology will also be used for the modification of existing foods, for example, the introduction of unsaturated fatty acids or production of fats yielding fewer calories. The science is straightforward, and there seems to be little consumer concern. A Mars bar which claims to yield fewer calories is already on sale in the US.

6. Then there will be many new plant products, of three general types;

- Modifications of the genetic material of plants to extend their shelf life by slowing down the enzyme responsible for the breakdown of the plant cell walls, for example the new tomato, and a melon to come; this will affect *quality*.
- Modification of the genetic material of plants to produce novel parental lines for the production of new F1 hybrids, for example rape, affecting *yield*.
- Modification of the genetic material of plants to introduce resistance to herbicides or pests, for example, both soya and corn, also affecting *yield*.

7. Then some suggestions, roughly in a time sequence, for plants, for both speciality and commodity crops:

- Continued development of rapid genetic typing methods to speed conventional plant breeding systems, leading to the identification of genes responsible for desirable traits, and their transfer to other species, for example between the cereals.
- Continued development of genetic manipulations, along the lines of herbicide resistance, involving one or more genes, with the production of plants resistant to many herbicides, and a wide variety of pathogens, including viruses, bacteria and fungi, thus greatly reducing or eliminating the huge losses due to these agents.
- Continued development of novel fertility systems, leading to the production of new F1 hybrids, with increased yields.
- Continued development of fruits and vegetables with longer shelf lives and better shipping characteristics.
- Modification of fatty acid synthetic pathways to produce oils containing different, and more suitable, fats and to produce starches for either dietary or industrial use.
- Genetic modification of fruits and vegetables with the aim of improving flavour, texture and nutritional content. Conversely, elimination of genes for toxicants and allergens.

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- Isolation, and utilisation of more complex genetic systems such as those controlling salt tolerance, drought resistance and response to day length, making possible the production of plants which can be grown in a much wider variety of habitats.
 - Isolation of the genes that control development means that we can start to manipulate flower shape, and colour for the horticultural industry.
 - Similar isolation of the genes that control the plant's response to day length means that it may be possible, by modifying these genes, to produce plants that come to maturity more quickly, and so push North, for example the Northern limit for growth of rape in Canada.
 - Production of drugs and vaccines in plants.
8. Developments in animals, apart from those leading to the production of high value/low volume drugs from transgenic animals will be slower; for here there is greater public concern. But some predictions are possible:
- Development of rapid genetic typing techniques will revolutionise animal breeding, enabling the identification of the genes critical for elite stocks and their transfer, using cattle, pigs and horses or poultry.
 - Similarly, the identification of genes for undesirable traits will accelerate our ability to remove them from breeding stock.
 - Better understanding of infectious disease pathogens should lead to the ability to breed animals with increased disease resistance.
 - Genes could be introduced to enable cows to produce milk that is much closer in its composition to human milk for feeding to babies.
 - A similar approach could be used to produce transgenic animals with, for example, less body fat. However it will, I think, be some time before such animals are acceptable for food.
9. How far have these developments got? It is well known that Monsanto's herbicide-resistant soya "Roundup Ready" is already on the European market, and there are many more such crops coming through. One way of finding out is to look at the list of those genetically modified crops that have been registered and are now deregulated for field testing in the United States. Sixteen new products in six crops were deregulated in the last year and a half, joining seven previously deregulated products, a total of 23. The crops include soya, cotton, rape, potato, corn, tomato and squash.
10. The first recorded field trials of transgenic crops were carried out in 1986; and by the end of 1995, over 3,600 field trials had been carried out across 34 countries with at least 56 crops. This year a total of about 30 million acres have been planted with transgenic crops, mostly in the USA and China. This year, nearly 15 per cent of the US soybean harvest has been grown from genetically modified seed, up from 2 per cent in 1996. China is thought to be growing over four million acres of genetically modified tobacco and tomatoes. The scene is very different in Europe; the EU's approval process for novel crops is slow, causing tensions with the US over the delay in permitting imports of genetically modified food supplies. There have also been difficulties in defining what has to be labelled and how.
11. What problems may be encountered with the introduction of these new crops? First environmental issues. Will transgenes escape to wild or weedy species, how far will the pollen from genetically modified rape spread, what will be the effect of volunteers on the next year's crop, will the cultivation of large acreages of insect resistant plants alter the insect ecology, will there be changes to plant associated microbes in the soil, will antibiotic-resistance genes transfer from plants to man through gut bacteria? The environmental issues are being carefully regulated by a committee, called ACRE. It is being careful and cautious, insisting on a series of controlled trials; and the pollen dispersal and the adjacent flora are being monitored to see if there is any spread of the GM crop. So far, GM crops behave in the same way as the unmodified crop.
12. The concerns arising from the widespread growing of GM has led the NFU to develop proposals for post-release monitoring, and very recently, the EC stated that they have now adopted the principle of post-release monitoring to "verify the non appearance of any harmful effects on human health and the environment". The details of this monitoring process are not yet available.
13. Then, as you know, segregation and labelling of soya and maize have raised major problems in Europe. Herbicide resistant soya was genetically modified by the introduction of a gene from a soil bacterium to make the soya resistant to the herbicide glyphosate. The ACNFP had no safety concerns, and labelling was not required. It did, however, recommend the provision of information on a voluntary basis by the retailer, the practise followed in the case of the successful launch of the paste from genetically modified tomatoes earlier in the year. In the case of maize, the ACNFP recommended against authorisation of this product for use in the UK because of the perceived risk of the transfer of an antibiotic resistance gene in the maize to the bacterial flora in the gut of livestock that had been fed the maize, with the eventual possibility of transfer to humans. This recommendation was overruled by the EC on a majority vote, but a number of EU members would not accept this decision, because of consumer pressure, and the situation has not yet been resolved. The maize is only to be used as an animal feed, and as a source of starch for food ingredients, and has yet to be imported or grown in Europe, though France has just been given clearance for Bt maize to be grown in 1998.

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[Continued

14. However, soya is now entering the UK, and the retailers have not been able to offer their customers choice between a modified and an unmodified product, because of the lack of segregation in the United States of the soya crop. This has meant that choice is effectively no longer available to the consumer in the UK, and soya is included as an ingredient in the majority of processed foods. It is not surprising that North American farmers are unwilling to segregate their GM crops, since there seems to be little demand for segregation in North America, while the costs of segregation would be considerable and would counter any benefit of growing them. The US government has supported the farmers in this stance by clearly stating that any attempt to ban the import of soya or maize would be considered as a breach of WTO agreements.

15. So despite the best efforts of the retailers, who have provided a range of useful information leaflets and a help line, there has been substantial consumer concern because of the absence of choice. It is therefore good news that the NFU has recently launched two complementary codes of practise for the growing of GM crops in the UK. The codes lay out guidelines to ensure traceability, via a seed package identifier plus accompanying information appropriate for on-farm record keeping, segregation, and the post-harvest documentation that accompanies each crop consignment. These procedures should ultimately allow foods that contain the material that was derived from GM crops to be labelled to ensure consumer choice. In the absence of segregation, a number of companies are developing tests to detect transgenic material so that foods that contain modified soya can be labelled. Experience with the modified tomato paste in the UK shows that consumers will buy a clearly labelled product, especially when it is cheaper than the conventional can sitting alongside it on the supermarket shelves.

16. However, the situation over labelling is still unsatisfactory. No doubt stirred by the public dissatisfaction earlier this summer, the European Commissioners proposed a labelling framework for products from GM crops. There were to be three categories. The first, which is *voluntary* labelling was negative; e.g., "This does *not* contain material of GMO origin", while the other two were *mandatory* and were either "This *contains* material of GMO origin", or "This *may* contain material of GMO origin". Then on 31 July 1997, the EU agreed that the rules should also apply to GM products that had already been approved for use in the EU, such as soya and maize. The exact labelling requirements for such products were to have been outlined by the EC in early November, but this has not yet happened. Mainly because of this confusion and delay, the IGD announced, on 20 November 1997, that their members were to introduce voluntary labelling guidelines for 1998 for products containing soya. They have decided that products containing soya should be labelled as "*containing*" GM soya. The "may contain" label is not to be used.

17. So, given these problems, why is the cultivation of genetically modified crops growing so quickly, as the figures I quoted earlier show? Herbicide-resistant soya has real advantages for the farmer. In the US, where Spring sowing is normal, the use of a post-emergent herbicide means some changes in agronomic practise, leading to retention of more moisture in the soil, and partly because of this, and partly because of the slightly longer growing season, and partly because of the effectiveness of the herbicide Roundup, the yields are significantly higher.

18. The introduction of these new crops will mean changes in the way farmers work. Monsanto are asking for, and obtaining, an increased price for the genetically modified seed, and also an agreement making it impossible to sell or sow seed from the harvest. The Company will also supply the farmer with a card that enables him or her to buy Roundup at a reduced price for use on the crop.

19. So, in summary the farmer in the US will soon be planting genetically modified crops on a wide scale, and it is inevitable that Europe will follow, although I cannot predict how much of a delay there will be. These new crops will however bring a much closer relationship between the farmer and the agrifood company, who will sell both seed and herbicides, and also a similar closer relationship between the farmer and the retailer, for complete traceability will be essential. There may also be a need for a licensing system of some sort to monitor, and, if necessary, control environmental issues.

Examination of witnesses

PROFESSOR DEREK BURKE, former Vice-Chancellor, University of East Anglia and former Chairman of the Advisory Committee on Novel Foods and Processes (ACNFP), called in and examined.

PROFESSOR JOHN BERINGER, Dean of Science, University of Bristol and Chairman of the Advisory Committee on Releases into the Environment (ACRE), further examined.

Chairman

34. Professor Burke, your attendance here is most appreciated. We have had the good fortune to see your recent address to the NFU. Would you begin by

explaining your positions, previous and present, in relation to the regulation of genetic modifications?

(Professor Burke) Thank you, my Lord Chairman. I was chairman of the Advisory Committee for Novel

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[Continued

[Chairman *Contd*]

Foods and Processes for nine years from 1988 to 1997. I came to the end of my term last September, but I have kept up my interest in the field and the media keep talking to me. For much of that period I was also Vice-Chancellor of the University of East Anglia, from which post I retired about two years ago. In that post I was Chairman of the John Innes Council, the John Innes Institute being the major plant-breeding biology research institute in this country. I have some previous experience in a biotechnology company in North America and also as a professor doing gene cloning at the University of Warwick. Professor Beringer and I are both scientists by background. We have been trying to steer through this new technology in an area which has aroused some controversy.

Lord Willoughby de Broke

35. ACNFP opposed regulatory approval for the maize produced by Novartis which contains both an insecticide and genes which in a bacteria, but not in the maize, would have conferred resistance to an antibiotic. ACRE was satisfied with the safety of the product. Can you explain the difference between the two committees' conclusions?

(*Professor Burke*) This is an interesting case study. Antibiotic resistance genes—that is, those genes that confer resistance against the action of a particular antibiotic - have been used widely in plant biology for the selection of new varieties from genetic modification for some time. Some years ago the committee that I chaired became somewhat concerned about their widespread use. We initiated a consultation in the early 'nineties and produced a guidance paper for the use of these genes in 1994. All of that predates the receipt of this particular application from Ciba-Geigy (as it was then). This maize contains a gene which confers resistance to the antibiotic penicillin. It was there because of the way that the genetic material had been constructed in the bacterial host before being put into the plant. It served no useful function in the plant. We were concerned with the low risk possibility of the transfer of this gene to gut bacteria in cattle when fed the unprocessed maize, the possible activation of the gene and the production and replication of those bacteria, with subsequent transfer into the human food chain, with the low risk of increasing antibiotic resistance in the human population through the human handling of those cattle. We are talking about a low-risk situation, and we have trouble dealing with very low-risk situations. The beef on the bone controversy is an example of that. Professor Beringer and I agree that these are lower risks than that. The committee was not against the use of antibiotic resistance genes as such. The flavour-saver tomato and the Zeneca tomato paste contain an antibiotic resistance gene which we considered not to be a risk, but we thought that this one was just over the boundary and we did not recommend approval. That went to Ministers who received different advice from Professor Beringer's committee. We had a first meeting in late 1995 to see if we could agree. We did not agree. However, we agreed on the differences. ACRE is concerned about evidence of

harm. It took the view that there was no increase in risk because the antibiotic resistance genes were already present to a considerable extent in the population. We believe that although that was true we should not be party to any action that increased that figure, even by a small percentage. In making that decision we were influenced by a medical member of our committee who was very concerned about antibiotic resistance and possibly the consumer representative who was also present. We are talking about a marginal decision in a low-risk case. They were more concerned about the environment, and we the particular food. They were subject to legal constraints, and we were dealing more with people's perceptions and concerns about these novel foods.

(*Professor Beringer*) Clearly, this is not an easy issue. ACRE took the view that the increment of risk was extraordinarily low. In anything we look at we do not assume that there is no risk of harm. All of the crops that we grow have within them some potential to cause harm, sometimes serious harm. For example, potatoes can be extremely poisonous. We are very used to the concept of an existing element of possible harm. Are we going to make something worse than it already is? After all, there is nothing much worse for the natural environment than agriculture. The basis of our decision was that about five per cent of people were already carrying these drug-resistant genes and the chances of that maize introducing those genes into humans and causing a health problem were unlikely to be as much as one in a million million, so it was quite low relative to five per cent. To us, it did not present a risk of harm. Therefore, we gave our approval. If one had stopped all prescriptions for ampicillin other than only in emergency use perhaps the view would have been rather different. But that is an extremely commonly used antibiotic. It is used far too often and irresponsibly and has a very high existing frequency of resistance. We did not believe that it would add to harm.

(*Professor Burke*) I tried this argument on the committee who said that nothing should be done to increase that figure, even by a minuscule amount. Therefore, one has two different attitudes to a currently agreed situation.

Lord Jopling

36. We have moved on a little. A number of us read an article that appeared in *The Times* on 4 May based on work carried out in Switzerland by the Swiss Federal Research Station for Agro-ecology and Agriculture in Zurich. It reads: "A team. . . has found evidence that the poisonous effects of the protein can spread further. It raised plant-eating insects on *B. thuringiensis* maize plants and fed them to the larvae of lacewings - which eat crop pests. They report. . . that the death rates of the lacewings nearly doubled. . ." The conclusion reached - that is, by the journalist - was that, "This means that an insect could nibble the plant, then fly off and be eaten by a lacewing, which would die." Here one has an area where there may be a domino effect that only experience can show up. Listening to the evidence given earlier by Professor

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[Continued]

[Lord Jopling *Contd*]

Beringer, it appears that there may be hidden effects. It may be a human being rather than a lacewing. Perhaps you would both comment on it. I know that this was a laboratory-scale experiment and that it might not be repeated in the field, but it gives rise to considerable concern.

(*Professor Burke*) This is more a matter for Professor Beringer than me because it deals with an environmental effect from a different gene. This is not the gene referred to a few moments ago but the so-called Bt gene that is present in this maize, and is the basis of the resistance to the corn borer which is a major corn pest. I also read that article which gave an example of an environmental effect upon the insect populations. We have considered the effects of Bt gene products on human populations. The evidence is that there is no toxic effect. In parenthesis, if we have any concerns about any potential toxicological effect on human populations we can refer the application to the Committee on Toxicology which may require a full toxicological analysis. We are looking at food, not environment. Professor Beringer is looking at environment rather than food.

(*Professor Beringer*) We have belt and braces as far as human safety is concerned. On ACRE there is an expert in allergenicity. We also ask questions about possible human or animal food safety. We always remind the MAFF people who are present to make sure that their appropriate committees look carefully into these for anything that we may approve for release. To go back to the lacewings, a similar report was produced in this country on ladybirds eating aphids from genetically modified plants. Yes, these are effects. The reality in terms of environmental harm is that if you keep your crop free of aphids by spraying the ladybirds will not have any aphids to eat anyhow and therefore will die. Likewise, if you kill all the insects on another crop the lacewing will not be able to eat them and the lacewing will also not multiply. This reflects what I said earlier. If one is to make crops intrinsically resistant or improve the use of pesticides one will reduce the amount of insects. One will have second-tier effects. But they are already in agriculture. There is nothing to stop one spraying as much as one wants to keep out every insect that gets anywhere near one's farm. If one travels with a MAFF adviser the advice that is commonly given is, "There's an insect there—kill it."

Lord Wade of Chorlton

37. How does one assess the risk? What becomes risky and what is not risky? Professor Beringer talked about a possible risk of one in a million million. The line was drawn at that. But would the line be drawn at one in a two million million chance? To me, that does not make the slightest difference to the risk. Every day I do something which is 10,000 times more risky than that. Cannot we begin getting a debate going about what risk we are talking about? What are these risks compared with the normal risks in life?

(*Professor Burke*) It is very difficult to put numbers on these. In the environment there are domino effects. Our committee has learnt to distinguish

between the safety of food, for which we have absolute responsibility—we must never approve of food that we believe to be unsafe - and the perception of risk in the population. The consumer makes judgments not based on absolute numbers. He or she is particularly concerned if *they*—the regulators, the Government, the House of Lords or whoever - take decisions which he believes impinges on his or her freedom of choice. Food is a particularly sensitive area. For example, we have barriers to certain foods. We do not eat horses and dogs, not for food safety reasons but for religious, ethical and societal reasons. Over the past nine years we have learned that whenever we talk about new foods we are likely to raise concerns of this kind. This is not irrelevant to the issue of labelling, on which Professor Beringer and I do differ. My rather pragmatic attitude is that, first, we have an absolute responsibility for food safety. Second, we have to deal as pragmatically as we can with the issues of perception which are particularly sensitive in relation to food. They are also sensitive in relation to the environment but they stem from a different set of values.

38. You did not answer my question but what you said was of interest. At some stage we must begin to evaluate this matter in a way that the public understands. Merely to say that something is risky given the enormous range is not particularly helpful.

(*Professor Burke*) I agree. One of the Ministers in the previous administration referred to a Richter scale of risk. We are not in a position to place a number on the risk when there are social implications and people distinguish between their choice and others' choices. They regard some things as so risky as to be totally unacceptable. The risk of a Chernobyl-type explosion is very low indeed but it is an unacceptable risk at any level. It is not a straight numerical calculation and that makes it a lot more difficult to deal with.

39. Can you explain to the committee your understanding of "substantial equivalence"? It would be useful if you could briefly outline how you see the novel food regulation being used for regulatory approval for the following three products: a fruit which has not previously been marketed in the EU but is commonly eaten in other countries, for example the durian; a peach modified so that the expression of new genes results in a much smaller stone, but the flesh of the fruit does not contain the gene products; and maize oil in which the maize has been modified to change the oil characteristics and where herbicide resistance has been used for selection of the modified crop? Would you also comment on ostrich meat, which a few years ago I would not have dreamt of eating but which is now available all over the place? Many years ago when I was in the cheese business I was the first person to use ultra-filtration as a method of manufacturing cheese. That was accepted and went into the marketplace. It was then a new process that had not previously been used for that product. Would that now be considered as a novel food?

(*Professor Burke*) To answer the last question first, the committee dealt with any novel process and any change in the way food was processed: food

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[Continued

[Lord Wade of Chorlton *Contd*]

sterilisation processes, neutron irradiation and so on. Novel foods included those which had not been genetically modified. The majority of our work lay in non-genetically modified food but novel foods that came into the country, sometimes sold in health shops, such as chaparral tea. Sometimes new fruits or oils came in. The committee was concerned with all novel foods and processes. We had to ask ourselves: What was novel? We adopted a broad definition and said that it was something to which the British population had not been exposed in the past. Reactions to foods depend sometimes on population differences. How does one assess the safety of such a novel food? We start from where we are; namely, populations all over the world have been eating foods for many hundreds of years. There is a considerable accumulation of folk wisdom about what you can and cannot eat, how it should be prepared, and so on. To return to the question, "substantial equivalence" means that you start by comparing the new case with what is already in the diet, preferably in Britain but possibly elsewhere. One uses the accumulated wisdom and experience of generations and asks: How close is the new material to what is already being eaten? Another reason for doing it is that one cannot screen novel foods in the way one screens novel drugs where commonly one gives to animals and ultimately to man much larger doses than will eventually be used. One cannot give people 10 or 100 times as many durians as anyone would want to eat. If one did there would be certain physiological effects! Substantial equivalence is not a precise definition but a judgment, and there is a series of criteria for it laid down. The committee will ask: How close to or different from is this from an existing food? If it is absolutely identical and the track record is very good there is no problem. One then asks: How different is it? Are any of these differences likely to give rise to a problem? How can we detect these problems? Ultimately, it is a matter of judgment. The committee works on a case-by-case basis, arguing about the possible risks that may ensue—in the presence of a consumer representative and an ethical adviser. Therefore, it is a process and not a dictionary definition. Going to your examples, you spoke of a fruit not previously marketed in the EU but commonly eaten elsewhere. Those are coming into the country all the time. If one goes into the market of any town one will find novel foods that may or may not have come before the committee. In general, the big importers and supermarkets are scrupulous. The small market trader may not bother. We would ask how widely durian had been eaten in the world by Anglo-Saxons, non-Anglo-Saxons, whites, non-whites and so on. Is there any suggestion that there may be a difference? What is the history? If it was clear that there had been no problems elsewhere and there was no reason to believe that there would be problems in Britain it would be cleared. Your second example was a peach modified so that it had a smaller stone. This is an interesting hypothetical example. I can only react as I would on the committee and say first, that I know nothing about what controls the size of peach stones. Presumably, a series of genes controls the size of stones because one can breed selectively for different

sizes of stone. I assume that a number of genes are involved. If so, there may be secondary effects from the alteration of those genes. Therefore, the committee will ask the person making the case to do detailed chemical and biochemical analysis on the peach flesh. Is there any reason to believe that it may be different? One would ask for all the things that one could think of. One might also ask about the things that had been bred out of the peach during selective breeding. For example, it is well known that potatoes in the wild carry toxic materials that have been bred out for commercial use. But if one genetically modifies potatoes there is a real risk that those toxic alkaloids may pop up again. In a situation like that the committee will nearly always go back to the applicant and say that it wants more evidence about this, that and the other. If it was worried it would go to the Committee on Toxicology. It is a reiterative process. We have tried to help applicants over the years by refining these kinds of questions into a series of decision trees which are published. The applicant traces his product through the decision tree with a series of yes/no answers. That should provide the information that the committee needs to make the decision. That is designed to prevent an endless reiterative process back and forth to the producer. The volume of material that comes in with an application such as the one that you instance may be an inch or so thick with a lot of detailed material because the applicant will be aware of the sort of things that the committee will be asking about. That does not mean that the committee does not go back and ask other questions. Your third example was maize oil in which the maize had been modified to change the oil characteristics and where herbicide resistance had been used for the selection of the modified crop. That has happened. Herbicide resistance maize is grown and the oil is then extracted. There would be no DNA and very little protein in the oil, so there would be almost no residue of the genetic modification. However, the oil would be different. We would be very interested indeed in the changes in oil composition. The composition of oils in the human diet is a very important part of our normal health. From genetic modification and other forms of food manufacture we have had a whole series of modified oils with increased unsaturated fatty acid content, for example to replace cocoa fat. Oils are being changed all the time. One can even buy a Mars Bar that is claimed to contain fewer calories so one can eat more of them. This is based on a change in the fatty acid composition in the fat in the Mars Bar. The committee spent a lot of time considering what would be the effect on the normal population of a change in fats. In this instance one ends up talking about the role of fatty acids and normal human nutrition. What are the effects of altering it? Should we allow people to alter it? As for ostrich meat, we never thought of eating it before but today it is available in supermarkets. You can choose to eat it or not. It is labelled. It is perfectly straightforward. The supermarket will be aware from the bar codes at the end of it how much ostrich meat is sold at any particular time to any particular group of people. The market will just run that. We may have

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greater problems where we cannot separate the new from the unmodified. But in the case of ostrich meat it is easy: if you do not like it, do not buy it.

40. I would have thought that that argument could be used for many other things. I do not see why only ostrich meat comes within that category.

(*Professor Burke*) I am told that supermarkets work on the amount of material moved per square metre of shelf. If something does not move it goes off the shelf very fast. They are running experiments all the time on supermarket shelves as to whether or not people buy certain products. I have a loyalty card and perhaps Members of the committee also have one. They tell us not only what we buy but what our socio-economic status is, where we live and so on. They have a huge amount of information as to how the market works.

Chairman

41. Under the novel food regulation MAFF is the authority which assesses the risk of modified foods and animal feeds. How are environmental concerns, if there are any, dealt with?

(*Professor Burke*) They would go to ACRE chaired by Professor Beringer. There is cross-membership. One member of ACNFP was also a member of ACRE, and there was also cross-membership of other committees. We would cross-refer it and not attempt to answer an environmental issue because of our lack of expertise. There are always civil servants who work with ACRE present at the meeting. That has never been a problem. That system of communication between a series of committees works well. What is sometimes lost is the big issue which does not fall into any one committee slot and is not part of any one remit. I think that that is something which the Food Agency will need to consider. Professor Beringer also referred to some of the bigger issues that did not fall within the remit of any one particular committee.

42. He referred to issues like fewer insects for birds, but that would not come under the Food Agency?

(*Professor Burke*) No.

43. Can you give an example of something that would come under the Food Agency?

(*Professor Burke*) Animal feed did at one time. Looking back over the period since the introduction of genetically modified soya, we were asked whether it was safe. We were confident that it was as safe as any product was likely to be. But we were not asked about the implications for the food chain of introducing a genetically modified material as a commodity foodstuff. I am not sure whose responsibility that is. That is an illustration of "the bigger issues", ie the effects downstream in the market of approving something that may have implications for farmers, grocers and so on.

Lord Moran

44. There have been a good many suggestions that in the interests of the consumer products should be labelled to show where a genetically modified

organism has been used. If there is to be labelling how should it be done? Should all products derived from GMOs be labelled as GM even where the gene and gene product are absent from the product, for example as in oils? Should the label indicate if the gene product is present but the gene probably is not, especially if the gene product is allergenic, for example with genes of nut origin, or if the processed product contains a small quantity of the GMO, for example a pizza which contains a small amount of soya bean oil or flour derived from GM soya?

(*Professor Burke*) The labelling issue picks up the two points that I tried to distinguish earlier. Food safety has no implications for labelling. There is no question of an unsafe food going through to the market. You do not label something as unsafe. You label because the consumer has asked for information about the amount of materials or their origin. At one time I thought that that such information was not needed, but I am persuaded that if the consumer wants information we should provide it. The difficulty is how it should be provided. How much labelling should there be, and what form should it take? What is both practical and informative? There is a trade-off between the two aims. One can take your particular example of the oil derived from rape where there is no gene product and no DNA present and the oil is substantially the same as normal oil. One can take another example which is a real possibility. If sugarbeet is modified to make it disease resistant should the sucrose derived from that sugarbeet be regarded as different from normal sucrose? Sucrose is a straightforward chemical molecule. It is crystallisable and has a defined chemical composition. In my view, one should not label that product as being different from normal because it is not different. There is no test that you can devise to demonstrate from where it has come. A label that cannot be tested in some way is of no use. In my view, if the product is indistinguishable from the conventional product then labelling is unnecessary, but if there is any difference at all - and here I am talking about the gene product not the gene, which is exactly what has happened in soya where there is a small amount of new protein but no DNA present in a non-biologically active form - then there should be a label. I used to think that labelling was not necessary but I have changed my mind. If the consumer wants to know he should know. The difficulty arises over the practicalities. As you know, soya is moved round in hundreds of thousands of tonnes. The tests for the presence of genetic modification are difficult and have a low level of sensitivity. There has been a good deal of confusion as to what should be done about such commodity crops. Last week I went to Tesco and when I got home I found that the label on a pizza contained a little asterisk at the bottom saying that the soya had been genetically modified. Because the EU has not yet reached agreement, Britain has moved ahead and provided labelling for soya. Soya is present in 60 per cent of products in supermarkets. I have some concerns about a label which appears on 60 per cent of products in supermarkets when there is no alternative,

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except if I go to Iceland. Who knows how long they can offer that alternative?

45. Clearly, it is very difficult to provide the sort of label that can be readily understood by the consumer and is more or less accurate?

(*Professor Burke*) Yes. This is a sophisticated science which is quite hard to explain. The science carries social overtones. The consumer has lost some confidence in the regulators, particularly in the light of BSE. The consumer does not know how seriously to take the case put forward by Greenpeace and the Natural Law Party. The consumer finds it hard to weigh the level of risk. We cannot put a number on it. But the consumer has the right to choose. We find it very difficult to supply the information that the consumer needs in a way that he can make use of it and so make sensible choices. But people do make choices. In the week following the BSE issue I stood beside a deep freeze in a supermarket. People were saying, "It's half-price and the risk is very low. I'm buying it." We make risk-benefit decisions all the time.

Lord Redesdale

46. You said that it was very difficult to carry out tests on genetically altered material. How do we ensure that imported products have been assessed and labelled correctly?

(*Professor Burke*) I think that this will be very difficult. There is a test for the gene which is sophisticated, expensive and involves the use of radioactive material and similar sophisticated biochemicals. It must have a lower limit of sensitivity. I do not believe that we can be sure. For that reason the EU Commissioners proposed a label which said "This may contain genetically modified material". That pleased no one. The manufacturers were placed in an impossible position. They had a label that they could not defend. Greenpeace did not like it because it believed that it was being fobbed off. What is the consumer to make of a label which says that certain products may contain such material? Particularly in the case of commodity crops I think that manufacturers to be sure that they are not misleading their customers will label all their soya products. The choice will arise either by a particular supermarket offering an alternative or, as in organic produce, by market segmentation within a supermarket chain. We are running a rather interesting social experiment to see how deep the concerns are. My general experience is that the British consumer is very pragmatic. He or she is cautious particularly after BSE but is not a hypochondriac.

Lord Grantchester

47. This has virtually been answered. How would you label?

(*Professor Burke*) I think that we must label. We as regulators must not be seen to have things to hide. If the public wants to know then it is reasonable to give them the information in an open democratic society. The difficulties arise in how that formulation

works. The matter is subject to some difficulty. The EU was unable to reach a decision in part because of the very different social approaches of different members. Professor Beringer referred to the differences between the US and Britain. There are also big differences between Britain and Austria. The EU has had difficulty in reaching a consensus. Quite recently the British have put a proposal to the Commission, which I believe is very sensible. I understand that that is to be discussed by Ministers in the next few days. During its presidency the British are making strenuous efforts to reach an EU-wide approval system for labelling. Of course, it will be a compromise; there is no other way to proceed. We live in a society that is different from that in America where new technology is not treated with quite the same caution as here.

Lord Rathcavan

48. Do you advocate a symbol for genetically modified labelling? You gave one example. I wonder what that means to the general public.

(*Professor Burke*) You can always supply more information, for example leaflets at checkout counters and so on. There has even been talk about intelligent PCs which can be interrogated. But that is for a very small percentage of the population who want to take it that far. There was talk—I am unsure of its current status—of a stamp or kite mark.

Chairman

49. But that is an example of voluntary labelling?

(*Professor Burke*) Yes—because of the failure of the EU to come to a conclusion and because supermarkets and manufacturers were rightly concerned to be as open as they could.

50. Would you be in favour of a threshold below which there should not be labelling, or do you think that any detectable presence of GMOs should require labelling?

(*Professor Burke*) As in all these situations, if any foreign substance is present one must have a lower limit. That lower limit can be set either by a toxicological test—that below that level there is no danger—or, more likely in this case, below the limit of detection. I do not know the limits of detection, but they are real.

51. And it will vary over time?

(*Professor Burke*) Indeed. The tests will probably become more sensitive.

Lord Jopling

52. You spoke of the complication of carrying out tests to see whether a product is genetically modified. How many places are there in the country which can carry out such tests? How long do they take? What would be the rough cost to a food manufacturer?

(*Professor Burke*) You may have to ask the Clerk to obtain some of that information. Any molecular biology research laboratory would be able to carry out

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the tests. It was something that I could have done myself when I was a little more involved. But it involves the use of very expensive chemicals and takes some time—a day or two. No standard county surveillance system is able to do that at the moment. I understand that specialist companies are beginning to spring up to offer this as a service. It will run basically rather like DNA fingerprinting. It will be a specialist service offered at a cost.

Lord Gallacher

53. We have dealt with labelling. Now we come to segregation. As some people are in favour of segregation of GM and non-GM food, do you think that that should be considered as a possibility, with non-GM food being treated in a way similar to organic foods? If consumers are given that choice, how do you suggest it should be handled? Perhaps it is more a matter for Sainsbury's than yourself.

(*Professor Burke*) Segregation is easy when the supply lines are short, for example when the products come from a local nursery. Zeneca went to a great deal of trouble to offer a separate line of GM and non-GM tomato paste. It becomes very difficult when a product has come a long way, though it is possible. There is an economic cost. The segregation of rapeseed was costed in Canada for about a year. It resulted in a 10 per cent increase. But it was said that that could not be scaled up because it was not possible to track the railway trucks. Everything had to be moved by road and such a major crop as soya could not be moved by road. Therefore, one runs into logistical problems of that kind. I am sure that it is possible but it comes down to cost. North America is going GM very quickly. The estimate for this summer is 40 per cent. I think that it will go to 100 per cent because of the advantages to the producer. American farmers are very independent people who make a shrewd decision as to what will give them the best income. This will give them more money and they will do it. Segregation can really take place only on the basis of countries, for example by Brazil or Argentina shipping the material separately, but terrible problems arise when one comes to the processing industry. Sixty per cent of the products in supermarkets cannot be segregated. I suppose that in retrospect soya flour from non-GM sources could have been offered for a few years, but I do not believe that it was ever practical to offer *this* particular product with and without GM soya. The costs would have been beyond what people were prepared to pay.

Chairman

54. But that is what Iceland does, is it not?

(*Professor Burke*) Iceland does it for its own label products. It does it by accessing soya from two particular countries. That is fine; that is how the market works. It is a very interesting experiment. If there is such an advantage to the farmer as the North American experience suggests the price cannot remain the same. Iceland will therefore have to pay

more to source that material and that will probably have to be passed on to the consumer. That is another very interesting experiment. How much more are people prepared to pay? I think that we should run these experiments. It is the only way in which we can find out.

Lord Jopling

55. I know that your former committee is not interested primarily in the environment. Is it conceivable that GM crops can have a net beneficial effect on the environment?

(*Professor Burke*) I had prior notice of this question and thought about it a bit. I offer two possibilities. The first is that if herbicide usage falls or simplifies—that is, people use better characterised herbicides—as long as we control what happens to hedgerows, the edges of lanes and so forth, then less herbicide is in general a good thing. Secondly, if yields rise we may begin to take out of farming less productive land, for example land at the edge of the sea coast. The sandlings of north Suffolk were ploughed up during the war. It is not very good soil. It would make a lot of sense to let it revert and devote a strip of land just in from the coast to insects and birds. Whether that will happen I do not know. One knows the pressures on farmers to optimise their income.

Chairman

56. Monsanto claim that huge quantities of insecticide do not now need to be used on GM crops in the United States which previously had to be used. Do you have any reason to doubt those claims?

(*Professor Burke*) No. I am just not expert to assess it. I think that it will be very interesting to watch it.

Lord Rathcavan

57. Do the delays apparently inherent in the EC regulatory system indicate an arbitrary and alarming inability to reach rational decisions within a sensible time frame or an admirable degree of caution and responsibility which contrasts favourably with regulatory practices in North America?

(*Professor Burke*) We are making very heavy weather of it. We are seriously in danger of losing competitive advantage in world agriculture. That is not a trivial problem. The agro-food world is now controlled by about five companies of whom only one is British. The WTO also has an impact on what we do. I hope that this committee will be able to help the tide that is necessary to get faster decisions out of the EU. A personal view is that the people who are making the decisions are not paying the costs of the delays in implementation. Whatever the decisions may be, delay costs money. Having said that, the US has de-restricted very substantially. I am a little more cautious than Professor Beringer about the risks involved. I think that we need to watch it. But if the Americans want to run the

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experiment let them run it. The US is moving very assertively in this field. It has taken a number of steps to free up the regulatory process not only in the areas of environmental safety and food safety but in the way it clears patents. Recently I heard that the Patent Office in the US was rewarded on

the basis of the number of patents approved, not the number of patents scanned. That is a very positive move if one wishes to be a dominant trading force in the next century, as I think the US does. We must respond rather more rapidly than we have so far. Chairman] Thank you very much for your most expert and valuable evidence.

WEDNESDAY 3 JUNE 1998

Present:

Gallacher, L.	Reay, L. (Chairman)
Gisborough, L.	Wade of Chorlton, L.
Grantchester, L.	Willoughby de Broke, L.
Jopling, L.	Young of Old Scone, B.
Moran, L.	
Rathcavan, L.	Clanwilliam, E.

Memorandum by Zeneca Agrochemicals and Zeneca Plant Science

Zeneca welcomes the opportunity to provide evidence to the committee.

ZENECA

1. Zeneca is a world leader in bioscience with its business and research headquarters based in the UK. The company invents, develops, manufactures and markets products to improve human health, nutrition and quality of life around the world. The company employs 32,100 people, of which over 7,000 are scientists, working in three separate businesses; Pharmaceuticals, Agrochemicals and Specialties. Over 94 per cent of Zeneca sales are outside the UK.

2. Zeneca Agrochemicals is the international business that develops chemical and gene based products for the agricultural sector; and were the first company to successfully launch in the UK a food (tomato puree) produced from genetically modified (GM) fruit. The business had a turnover in 1997 of £1,613 million. Zeneca's agrochemical business is the third largest in the world. In addition, Zeneca is co-owner of Advanta, the world's fifth largest seed company with its headquarters in The Netherlands.

3. Innovative research, coupled with effective product development and marketing skills, is the foundation for Zeneca's present and future success in agriculture and food. Zeneca Agrochemicals has 1,200 people directly involved in research and development, and this year is investing £140 million in this activity. To achieve the critical mass necessary for productive research most of the investment is based in the UK.

ZENECA'S RESEARCH STRATEGY

4. Zeneca's research strategy is based on the philosophy of *Integrated Crop Management* (ICM)—the use of the appropriate combinations of agronomic, chemical and genetic techniques, to optimise food production and crop quality. ICM is an approach that enables the farmer to conserve and enhance the environment, whilst producing safe and wholesome food economically. In farming, like in other business enterprises, commercial success is dependent upon making the best economic use of available resources. Getting the balance right is the fundamental tenet of this agricultural philosophy.

5. Biotechnology plays a major role in Zeneca's research programmes. For example, biotechnology is critical to the invention and evaluation of new generations of superior chemicals, new crop varieties resistant to pests and diseases, and plants with desirable traits such as enhanced yield and nutritional characteristics.

6. We believe that biotechnology has the potential to have a profound and beneficial impact on agriculture and the environment. Biotechnology will contribute to the development of sustainable agricultural systems in developed and less developed economies and hence increase agricultural productivity to help meet the challenge resulting from the projected population increase. The underlying science supporting biotechnology is describing the genetic basis of all aspects of plant growth, metabolism and development. Plant genome descriptions will give a full catalogue of useful genes and allow focused efforts to catalogue and conserve biodiversity at the gene and species level. Genetic improvement through knowledge-based breeding or through genetic modification will be enhanced by these genome programmes.

7. The first products developed through use of genetic modification are ones where single gene traits are providing major effects in crop protection (herbicide selectivity, resistance to insect attack or quality changes). As the technology develops, then more complex gene combinations will result which give improved effects. Integration of chemical and genetic effects to provide crop protection solutions is an area where we see great opportunities, particularly in the control of fungal and insect attack. On the same timescale, the knowledge of the fundamental makeup of plants and their pests and diseases will allow the more rapid identification of superior (cost effective with even lower environmental impact) chemicals for crop protection. The end uses of crops are enormously varied. Biotechnology will allow in the future the better tailoring of the raw material attributes of

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the crop to the specific desired end use, be this for optimum animal or human nutrition, or the production of specific feedstocks for industrial processes on a renewable basis.

INFLUENCE OF REGULATION—THE UK EXPERIENCE

8. The UK was a pioneer in the development and implementation of regulations which cover biotechnology; this is generally considered one of the reasons for the success of biotechnology in UK academia and industry. Zeneca feels that it played its part in the development of the regulatory strategy. These regulations were science based, carefully thought out and implemented. They have been respected and copied around the world. Zeneca was generally very impressed with the manner in which both the environmental and food regulations were applied in the UK. However, at the European level despite very positive statements on the importance of biotechnology for European competitiveness and funding of research, the regulatory situation is a cause for considerable concern.

INFLUENCE OF REGULATION—THE PRESENT SITUATION

9. To be successful Zeneca has to plan its research at least 10–20 years ahead. This is because of the long invention and development times in agriculture, due partly to the need to evaluate the products under different agronomic conditions and partly the time needed to gain regulatory approval. For example, we are just now launching Amistar one of a new generation of fungicides. Amistar is based on a natural product and has taken seven years to go from discovery to the market (the average period for an agrochemical is 8–10 years). We are however, already evaluating strategies for using biotechnology to control leaf disease in bananas and potatoes. The first field trials of the genetically modified banana plants will take place this year, but it will be another six years before we can offer disease resistant plants to the farmer as part of an ICM package. Regulatory uncertainty is a major issue in research planning.

10. The regulatory problems we face today are indecision and a lack of leadership at the European level. This is having a negative impact upon our business both directly and also indirectly via the damage it is doing to consumer perception. The main problems which affect our business are discussed below.

11. *Failure to develop the European regulations at the same pace as the technology has progressed.* For example, the UK has had novel food regulatory guidelines for many years. It was the existence of these well respected guidelines which enabled us to launch the GM tomato puree in 1996. However, it was only last year that the European Novel Food Regulation became law, yet it was obvious for many years that such a regulation would be needed. We believe that discussions on this regulation started at the European level in 1990. At the time of preparing this evidence there are still no clear European Union labelling guidelines for genetically modified foods. The industry has had to develop its own voluntary guidelines without any consistent guidance from governments; the resulting confusion leading to a lack of consumer confidence. Meanwhile the USA has in place a regulatory process which is widely respected by both industry and consumer.

12. *Potential conflicts between different regulations.* The European regulation defining organic products (2092/91) was carefully framed to “increase credibility with consumers” and to “ensure fair competition between producers”. The regulation, which covers imports, as well as crops grown within the EU requires that “95 per cent of the ingredients” are obtained in accordance with conditions laid out in the regulation. In June this year the European Council of Ministers will vote on amendments to this regulation which states that “in organic production, genetically modified organisms, parts thereof and products derived therefrom must not be used in products labelled as from organic production”. If this is interpreted as 100 per cent exclusion of any pollen from a genetically modified crop then this badly framed amendment will damage both the credibility of the organic label and the viability of European agriculture.

13. *A lack of transparency,* not only for the applicant but also for the consumer, in decision making. As a company we welcome any attempt to increase transparency.

14. *The scientific base* of the regulations is being diluted by political compromises. Society handles uncertainty by using the principles of risk assessment and then giving this advice to our elected representatives and leaders for a decision. The questions on biotechnology asked by the European and American regulators are very similar, which is not surprising since they are based on a scientific approach to risk assessment. To ask the regulator to provide a political, commercial, sociological or ethical decision is both a misuse and abuse of the scientific risk assessment approach.

15. *The sound bite approach to risk assessment.* In our view it is as wrong to state that all applications of biotechnology are safe, as it is wrong to state that all applications are dangerous. An important component of risk assessment is the case by case approach. The universal genetically modified crop plant does not exist. Each species and inserted trait must be dealt with independently. For example, the likelihood of outcrossing from varieties of tomato, maize, sugar beet and oil seed rape are totally different and must be evaluated differently. Similarly, the hazards of particular traits that may be inserted must be evaluated independently. It is scientifically

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dishonest and misleading to decision makers and the public to argue that the risks posed by crop plants with totally different agronomy and ecology are the same.

16. *A conflation of different issues.* Genetically modified crops have become the lightning rod for a debate on many other issues, such as agricultural reform, WTO and biodiversity. Genetically modified crops are usually only a small component of these discussions, but become the focus for the debate because that debate is not being held, or perceived as being held, elsewhere.

17. *International trade.* As at the European level, the regulatory implications of the transfer of GM seeds and plants between countries (and hence international trade) has been apparent for some time. The committees advising the Dutch and UK governments on the release of GMOs in late 1994 proposed guidelines to cover this issue. They in time evolved to become the UNEP "International Technical Guidelines for Safety in Biotechnology". We are now debating the BioSafety Treaty under the Rio Convention (which has not been ratified by the USA). Unhelpful trade disputes are the inevitable consequence of these different regulatory processes.

CONSEQUENCES

18. *Direct cost and delay* is the first result of this lack of regulatory leadership. There is a no clear regulatory route map for either academia or industry to follow. In preparing the case for a development decision on a product, the time and cost taken to achieve regulatory approval is one of the most critical factors. It is simply not possible to define this time and cost for a product entering the European Regulatory System. The time taken for the regulatory approval of genetically modified tomatoes indicated this issue. These regulatory applications are essentially for the same product.

Type of application	Submission date	Approval date
USA to grow and process	February 1995	June 1995
USA human consumption	September 1994	April 1995
UK human consumption	August 1994	January 1995
Canada human consumption	December 1995	June 1996
Mexico to grow and consume	June 1996	September 1996
EU to grow and process	November 1996	still no decision
EU human consumption	March 1998	

In the absence of an appropriate EU regulation it was only possible to launch the product in the UK which has a long history of regulatory guidelines for novel food. After receiving the regulatory approvals the product went on sale in Safeway and J Sainsbury stores on 5 February 1996. The cans of puree are sold next to the regular product which is produced from fruit grown in Italy. The transgenic tomatoes were grown in California. There is still no regulatory approval to grow and process these tomato plants in Europe.

19. *Effect on innovation and UK competitiveness.* The lack of predictability means that some of our most senior staff have to devote their time to steering the company through this state of regulatory chaos. Small companies, universities and research institutes do not usually have these skills available and therefore tend to concentrate on less contentious, though arguably less innovative, areas. In addition, potential investors are naturally concerned about uncertainty in product development. In our experience there is in the EU, compared with the USA, a dearth of entrepreneurial SMEs in the agricultural and food areas. One reason for this we would suggest is the regulatory system.

20. *Public acceptance.* The confused regulatory system does nothing to build the trust of the consumer in the regulatory system, those who administer the regulatory process, or the underlying political system. Without the political leadership to develop and defend the regulatory system, the way is open for the present spate of totally unjustified claims about safety to be made. The success of the genetically modified tomato puree sold in the UK stores of Safeway and Sainsbury was, we believe, partly because of benefits for the consumer, regulatory approval from HMG, the provision of information and clear (voluntary) labelling. The success shows that the European consumer will accept these biotechnological products provided they are treated with respect.

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APPENDIX 1

Press release by Nottingham University, 4 June 1998

NOTTINGHAM UNIVERSITY RECEIVES FIRST ROYALTY PAYMENT FROM ZENECA
FOR USA GROWN GM TOMATOES*Plans revealed for European grown GM tomatoes**Names of genetically modified tomatoes announced*

A milestone in research collaboration between academia and industry was reached last night when the University of Nottingham received from Zeneca the first royalty payment for its research on genetically modified processing tomatoes.

The tomatoes, grown in California, were used to produce tomato puree. This was the first food produced from genetically modified fruit offered for sale in the UK (or Europe) and has been sold over the past two years in the stores of Safeway and J Sainsbury. The tomato puree—on sale in cans clearly labelled as GM food and sold side by side with the non-transformed variety—has been very well received by the consumer.

The modified tomato was based on joint research by Professor Don Grierson, of The University of Nottingham, and Zeneca. The product was developed by Zeneca and the Petoseed breeders at Seminis, the world's largest vegetable seed company.

The tomato ripens normally but softens more slowly. This processing tomato offers benefits throughout the supply chain; the farmer and processor can get better quality fruit to the factory, while the consumer is offered quality and cost savings.

Sir Colin Campbell, Vice-Chancellor of the University of Nottingham, received the first royalty payment from Dr David Evans, Research and Development Director—Zeneca Agrochemicals, as a result of the UK sales.

"The development of the tomato puree is a case study of how a successful research collaboration between academia and industry as well as between different companies in the agri/food chain can lead to the launch of a successful new product. It signifies the start of an exciting future" said Dr Evans.

Sir Colin said, "The University of Nottingham is proud to be associated with a successful partnership between Zeneca, Seminis, Safeway and Sainsbury. The success of this product is proof that the consumer wants the benefits that biotechnology can offer, provided that they are fully informed and treated with respect."

Henk Pennings, Seminis associate director of research and development for Europe, said that "the alliance proved to be an optimal blending of "hardware", the Petoseed tomato, with "software", the Zeneca/University of Nottingham gene-isolation technology. Pennings also paid tribute to the contributions throughout the food chain, including Zeneca, the retail partners and ultimately consumer preference and choice. "We look forward to many more successful endeavours in the future" Pennings commented.

Pennings announced that the names of the first two transgenic tomato varieties for Europe would be "Vegadura" and "Vegaspeso".

Following the success of the genetically modified tomato puree in the UK, Zeneca and Seminis have applied for the necessary regulatory approvals from the European Union to grow "Vegadura" and "Vegaspeso" tomatoes and to sell them as processed products.

Further Press inquiries, etc.

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Notes for editors

1. The genetically modified tomato puree was first sold in stores of Safeway and J Sainsbury on 5 February 1996. The tomato is modified to produce lower levels of the enzyme polygalacturonase, this means that the fruit ripens normally and stays ripe in the field for a couple of days longer. The result is that better quality fruit can be delivered to the manufacturers for turning into processed food products. The first product is tomato puree sold in Safeway and Sainsbury stores. Once European production has begun we will see other processed products (particularly diced) being offered for sale.

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2. *Zeneca Group PLC* (Registered Office, London) is a leading international bioscience group with a turnover in 1997 of GBP 5.19 billion.

3. *Zeneca Agrochemicals* is the crop protection and plant science business of the Zeneca Group. It is the third largest supplier to this international market, with sales in 1997 of GBP 1.63 billion in over 130 countries.

4. *Zeneca Plant Science (ZPS)* is the business unit within Zeneca Agrochemicals which researches, develops and delivers value-added crop characteristics to growers and processors through the application of biotechnology.

APPENDIX 2

Press release by Seminis Vegetable Seeds, Inc, 4 June 1998

SEMINIS-ZENECA ALLIANCE PRODUCES SUCCESSFUL BIOTECH TOMATO PRODUCT IN UK

SATICOY, CALIF.—A research and development alliance between Seminis and Zeneca Plant Science has yielded a genetically modified tomato product that consumers in the United Kingdom favour two to one over its traditionally developed counterpart, according to officials at Zeneca.

Tomato varieties developed through a collaboration between Petoseed breeders at Seminis and Zeneca Plant Science of London are being used to produce a canned puree that shoppers in the United Kingdom have enthusiastically received.

Since its introduction two years ago, the product has outsold its competition, made from traditionally bred processing tomatoes, by a margin of two to one. More than 1.6 million cans of the puree were sold from the time of its introduction in February 1996 through November 1997. The tomato puree is marketed to consumers through the Safeway and J Sainsbury grocery chains, both based in the United Kingdom.

Officials of both Seminis and Zeneca say the reason for the product's success is a combination of collaboration among the companies through the entire research, development and marketing chain, as well as a focus on consumer preferences.

The new hybrids were developed to improve the quality of tomatoes used to make such processed foods as sauce, ketchup, paste, and pizza topping by decreasing the amount of an enzyme responsible for the breakdown of pectin, the natural "glue" that holds together the cell walls of fruit and vegetables. Zeneca isolated key genes responsible for the deterioration, while Petoseed plant breeders employed sophisticated processes to develop the hybrid varieties.

Since these varieties experience less softening prior to processing, they offer growers and processors the economic benefit of reduced tomato loss and spoilage during harvest and transport. The processing tomatoes also feature a thicker wall, which increases quality and efficiency at all phases of production, from harvesting to cooking to canning, providing the consumer with a quality product at a reasonable price.

The Zeneca-Petoseed collaboration is the first commercial introduction of a Seminis product developed with the help of biotechnology. The alliance proved to be an optimal blending of "hardware", the Petoseed tomato, with "software", the Zeneca-University of Nottingham gene-isolation technology, said Mark Stowers, vice president of the worldwide marketing for Seminis.

"We're pleased with the results of this initial project and we look forward to collaboration on more successful products for the future", Stower added.

The new varieties, named Vegadura and Vegaspeso, have been evaluated extensively in the United States by the Food and Drug Administration and Department of Agriculture and found to be safe and "substantially equivalent" to traditional tomatoes in all areas, including nutrition. Subsequently, the governments of Canada, Mexico, and the United Kingdom also approved the processing tomato hybrids for introduction to their markets.

The products will be cleared for sale in Europe pending approval under the Novel Food and Novel Food Ingredients Regulation, a necessary process for products developed through biotechnology and planned for sale in the European market, according to Zeneca officials.

Note for editors:

Seminis, based in Saticoy, California, is the world's largest developer and producer of vegetable seed. Seminis markets products in 123 countries through its Asgrow, Bruinsma, California, Genecorp, Petoseed and Royal Sluis brands.

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APPENDIX 3

Press release by The University of Nottingham, 27 May 1998

TOMATO PUREE FROM GENETICALLY MODIFIED FRUIT BRINGS FIRST ROYALTY PAYMENT FOR THE UNIVERSITY OF NOTTINGHAM

The University of Nottingham has received its first royalty payment for landmark research on genetically modified processed tomatoes.

The tomatoes, grown in California, were used to produce tomato puree—the first genetically modified food ever produced in Europe. The puree has been on sale for two years at branches of J Sainsbury and Safeway, in cans clearly labelled as genetically modified food—and consistently outsells the non-transformed variety.

The puree is the first product to be generated from pioneering work on ripening genes carried out at Nottingham over the past 25 years by Professor Don Grierson and his research team, in partnership with Zeneca Plant Sciences. As a result of Professor Grierson's work the modified tomato ripens normally but softens more slowly. The tomato offers benefits throughout the supply chain; the farmer and the processor can get better quality fruit to the factory while the consumer is offered improved quality and cost savings. The product was developed by Zeneca and the seed company Seminis.

Although the first royalty payment involves only some thousands of pounds, the research project overall has generated more than £1 million in funding for the University of Nottingham. Professor Grierson, who is based at the University's Sutton Bonington Campus, said the first royalty payment demonstrated that years of research which had received increasing scientific acclaim had also proved commercially beneficial. "The work produced the first ripening gene to be discovered and involved the first use of the 'gene silencing' technique to improve the properties of any food crop.

Examination of Witnesses

DR NIGEL J POOLE, Group Manager External & Regulatory Affairs, DR DAVID A EVANS, Research & Development Director, and DR SIMON W J BRIGHT, Technology Interaction Manager, Zeneca Agrochemicals and Zeneca Plant Science, called in and examined.

Chairman

58. Good morning. May I welcome you to the Committee and thank you very much for coming to assist us with our enquiry into genetic modification in agriculture. Could I ask you first of all to introduce yourselves and say what your different responsibilities are?

(Dr Evans) Good morning. My name is David Evans. I am the Research and Development Director of Zeneca's agricultural businesses. On my left here is Nigel Poole who is responsible for regulatory affairs and public affairs for our biotechnology business. On my right we have Simon Bright who has led much of our biotechnology research in recent times and presently is responsible for technology collaborations. Nigel and Simon have spent just about all of their careers in biotechnology and have worldwide reputations in this field. Indeed, both are honorary professors at universities. In addition, Nigel is a member of the Advisory Committee on Release into the Environment.

Chairman] Thank you very much. We have your written evidence, for which the Committee is grateful. Perhaps we can go straight into questions and ask Lord Gallacher to start.

Lord Gallacher

59. Dr Evans, what are the most important implications of this technology for agriculture, consumers and the environment?

(Dr Evans) Essentially as an international company Zeneca operates in over 146 countries. Indeed, 96 per cent of our sales are generated outside the United Kingdom. We take a worldwide perspective on this issue. Of course our headquarters and our research are based in the United Kingdom. Biotechnology is absolutely critical to our research programmes, in future product offers and in the integration of crop management technologies. We believe that biotechnology provides distinct consumer benefits in three major areas: first, productivity, then quality, and then variety. In terms of productivity, in my lifetime it has been necessary for the world to increase its food production three-fold and, given current population trends, that is bound to continue and we shall need to optimise the inputs from technology to meet those targets. In addition to population growth, food security is also impacted by the requirement, the desire, for quality and variety in food, particularly in developing countries, so we have a major job to do and we require the technology there. Within this biotechnology plays a vital role. Biotechnology regulation is our contract with society to allow us to develop safe products to present to this integration of crop management technologies. From my viewpoint

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[Lord Gallacher Contd]

what is necessary for Zeneca is that my job is about investing in research and development plans. We require a framework of regulatory clarity to allow us to make optimal choices in what and where and how we pursue our research and development aimed at these ends.

60. What crops are being worked on at the present time? Is the focus still on herbicide and pest resistance or has it moved to developments of more direct benefit to the consumer?

(*Dr Bright*) Biotechnology techniques are being applied essentially to the full range of crops which are being improved through breeding and selection means, so this is another tool to the armoury for crop improvement. The initial focus is on single gene traits such as modification for herbicide selectivity or insect resistance. The new crop protection genes and technologies which are going to come will do things which are more difficult than the first generation products, such as controlling fungal diseases and controlling difficult-to-get-at beasts such as things which attack roots. As well as improving crop protection and crop productivity, there is an increasing amount of research going on around the world and in our company on things to do with understanding what is the genetic basis of quality and then doing something about it. If I could give a couple of examples, we are interested in how the genetic basis of flavour works and how that can be improved. We all know in principle that eating vegetables is good for you. We can now begin to get at the underlying science, the genes that control the production of nutrients so that you can then have programmes to improve the nutritional qualities of fruit and vegetables. That is an example of a direct quality attribute. We also have work going on which has its primary benefit in environmental improvement. For instance, we have got a research programme where, by expressing a particular enzyme in a plant that goes into chicken food, you can then reduce the amount of phosphate pollution that comes out of intensive chicken farming practices. There is a whole range of activities both within our company and in other companies and to my mind this is something that is going to be very pervasive technology which will provide extra choices on how you do things in agriculture, both for productivity and for quality improvements.

Lord Rathcavan

61. You mentioned, Dr Evans, that you operate in 146 countries, I think, and you said that your developments were of particular relevance in developing countries. Perhaps you could enlarge on that and tell us something about what crops you are working on in less developed countries' agriculture.

(*Dr Evans*) The first point to make is that by means of enhanced crop protection technology does allow countries to grow crops which hitherto were not possible. One good example would be bananas which suffer from a very debilitating disease which is presently not well controlled by current technology.

Providing solutions to this problem (it is a disease called black sigatoka) is one of our research objectives. In addition to crop productivity it is clear that our technology worldwide provides benefits to the productivity of food, in other words the yield enhancement of food, in many countries. The technology is applicable to crops in general.

62. What percentage of your research or expenditure is going in less developed countries' agriculture as opposed to that of developed countries?

(*Dr Evans*) We have a crop list which is relevant worldwide. Essentially we operate worldwide so I find it difficult to give an exact answer to that. Our perspective is entirely global. The United Kingdom is actually a rather small percentage of our market and we have to operate globally. For example, in crop protection we are certainly number one or number two in Asia. In the world we would be number three, so our perspective is entirely international.

Lord Jopling

63. I can remember being told 10 years or so ago by Lord Rothschild that one of the things that would have the biggest effect on the agriculture of less developed countries would be if you could create a wheat which had a capacity for fixing nitrogen from the atmosphere. Could you tell us what you are doing about that and what prospects you see for that sort of wheat being produced?

(*Dr Bright*) Ten years ago I had that on my list of things which were impossible and I have now moved it on to my list of things which are just very difficult. The underlying science about what is required to make that productive symbiosis is coming along. It is quite clear that this could have a benefit. As a research manager I am still dubious about advertising when we can crack that problem. It is certainly very difficult, but I think it is one of the things if you like that you can put out there as an aspirational target to say, "I would like to understand how that works", and by doing that you can either replace or supplement fertiliser application. I would not hold my breath and say that within the next 10 years there will be a product like that. I think it is very difficult.

Lord Rathcavan

64. Can I move on from the speculation area into an area where you have achieved a product in the market and ask you at what stage is your application for growing GM tomatoes in the European Community?

(*Dr Poole*) I think a bit of history might help first of all. This was an invention in Europe but we did most of the development in the States. We then wanted to try and bring it into Europe because the process in this kind of technology suits our invention much better in Europe. We decided to bring it to the United Kingdom first of all and there were several reasons for that. One of the most important reasons was that at that time the United Kingdom already had some very well respected regulations and, apart from the

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[Lord Rathcavan Contd]

Netherlands, no other European country had those regulations, so we were able to get that comfort. We have to have a regulatory framework before we can bring a product on to the market and that was in place. It was a United Kingdom invention, the United Kingdom is our base, and I suppose we were also getting rather fed up with being told that Europeans are Luddites and would not dream of eating modified food. We wanted to test that and we also wanted to test whether our approach to the market and working partnerships would actually work. As you know, we brought it in in 1996. To date we have sold well in excess of 1.6 million cans in Safeway and Sainsbury. All that is sourced from California, it is processed in California and it is shipped over here. It is sold side by side with tomato puree produced in Italy. I suppose if you like we are putting Italian farmers out of jobs. We have now asked the European Union if we can grow and process this in Europe—it will grow in the southern states. That application we deliberately held back for 17 months in the hope that there would be some clarity in the European regulatory system. We submitted it via Spain and it is now 17 or 19 months since we had it submitted. Spain approved it, it has gone to Brussels, it has gone out to the Member States. It was considered by the Scientific Committee of Plants a month ago, which we believe is a favourable report. We are now waiting to go through the next steps. In our written evidence we have given the timescale of going through US, Canada, Mexico as well, so you can judge the timescales.

65. So it will not be until 1999 at the earliest?

(Dr Poole) We will not be planting and growing commercially until 1999. This is the growing season. The tomatoes are in the ground already. It is too late this year.

Chairman

66. Is there any particular reason why it is being held up as far as you know?

(Dr Poole) No; I think it is going quite fast through the European system compared with other products. There were two objections. One was from Austria on the presence of kanomycin, and one was from France on a general issue about genetic modification, but both those were considered by the Scientific Committee and we are waiting for their official report now.

67. As far as animals and fish are concerned are you doing any work in the genetic modification of either?

(Dr Evans) No, we are not.

Lord Wade of Chorlton

68. First I ought to declare an interest as a farmer and as a non-executive director of a company which deals in international trade on meat products, fish and milk products. I would like to ask you about the difference between the EC and the US. Would you comment first on the differences between the EC and the US approval processes from the point of view of

the applicant, both in theory and in practice? Then I would like you to comment on your experience of bringing GM food crops from the US to the EC.

(Dr Poole) We have worked in many countries. If you look not just at the US but Canada, Mexico, Australia, you actually find the questions you are asked are very similar to the ones you are asked in Europe and that is not surprising because all those countries are using a risk assessment system to evaluate the risk and make a decision. That is a scientifically based system and is a worldwide approach. The questions are the same. The amount of detail in Europe is slightly more but the difference we find comes in the next phase. It is actually deciding on those answers we have offered. That is where we seem to be hitting problems. This lack of transparency about the whole process and who makes the decisions is a real problem to industry at the moment. We need a route map, as Dr Evans said. Our most important criterion for a decision to develop a product is a clear regulatory route map and at the moment it is very difficult to get that in Europe.

69. Could you tell us about your experience of moving GM crops from the US into the EC?

(Dr Poole) As a company we were the first to bring into Europe a product which was approved in the States and sold in the States. Frankly we had no problems with those tomatoes.

Lord Jopling

70. Lord Chairman, I am afraid I neglected to declare an interest in the last question I put. I am a farmer. I also have some shares in your company. We have had a document from our specialist adviser on "The Gaps in the Regulatory Oversight of Biotechnology in the United States". You have not seen this. There was a briefing for the Committee. I will read to you two sentences at the beginning. It was a briefing for this Committee. He says: "There is no regulatory system for ensuring the safe use of biotechnology in laboratory or factory use where the organism is not to be released into the environment." He goes on to say a little later: "The United States Government decided there should not be special legislation to assess the safety of the products of biotechnology." I find that in rather startling contrast to the comment in your paper, paragraph 11, at the end, and again I quote: "Meanwhile, the USA has in place a regulatory process which is widely respected by both industry and consumer." I do not know if you would like to make a brief comment but what I think would be helpful is if you could take Dr Kinderlerer's paper away with you and let this Committee have your comments on it because there seems a very clear contradiction between what you are saying and what he is saying.

(Dr Poole) There is actually not a contradiction. May I develop it? First of all, in our presentation we are talking about a deliberate release into the environment and not laboratory work. Way back at the end of the eighties both the United States and Europe were considering how to frame their regulations, and

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[Continued]

[Lord Jopling Contd]

we have to go back right into history. The Americans said they could actually, under their law (which is a different legal system from ours in Europe) fit in the biotechnology regulations under products' legislation. To get approval for example for the tomatoes we had to get approval from the United States Department of Agriculture to grow them, to transport them and to process them at the federal level. We also had to get state level approval if we crossed state lines. The US GM law is under plant protection legislation they have already got in place, and to consume it you have to ask the FDA if they can see any reason why this product should not go on the market, which is again a catch-all phrase they use in their legislation. That regulatory legislation did not exist in Europe. At that time, remember, we were still individual European States. We were moving towards a European environmental process in 1992, and therefore Europe decided to set up its own legislation. I come back to my original comment that when you get down to it the scientific questions we have to answer in both lots are virtually identical.

71. Could I ask you whether you would send us a report on this?

(Dr Poole) Yes, of course.

Baroness Young of Old Scone

72. You have already told us quite a lot about your experience of the EEC regulatory system on the tomato issue. On other issues, or indeed on the tomato issue, have you had a different sort of experience depending on the EEC country you have applied to for approval?

(Dr Poole) We have worked in the Netherlands, France, Spain, Greece and Portugal. I think as a general statement we are extremely impressed with the regulators, the people who have to carry out the regulations, in all those countries. We find them very professional. I suppose you would expect us to say it, but we are very impressed with the United Kingdom regulatory system in place. We think it works very well for the United Kingdom. The problem in the other countries is that you get buffeted by political issues which can cause confusion and that is where the delay comes in. The track is actually better in the United Kingdom than in most other countries. It is pretty good in the Netherlands as well. Once you go into countries with less experience, naturally they are trying to build their experience and you start being asked about issues which are not part of the risk assessment.

73. And these are being asked by the regulators?

(Dr Poole) They come through the regulators because that is who we are communicating with. I am not au fait enough with the political system in those countries to say who is actually originating it. You are asked questions about public acceptance, or "Will our farmers accept it?", which are not part of risk assessment. You are asked, "Is there a need for it?", which is not part of the risk assessment process which is concerned with safety.

74. If I could apologise, I should have declared an interest before I began my questioning. Perhaps I may

do that now. As Chairman of English Nature, the Government's statutory adviser on biodiversity, I have an interest in biodiversity, and I am also a member of the Minister of Agriculture's advisory group. Can we move on to the issue of company responsibility, or indeed anybody's responsibility, in this field. Do you think the company should have a responsibility, for example for consulting stakeholders?

(Dr Poole) I would like to take that back again to the tomatoes because it does show the way we like to work. You need many other things to come together, not just to bring the product out but to make a commercial success. The stakeholders are an essential part of that. When we started the launch of the tomatoes we communicated—and, I want to emphasise, we listened to—many different parts of society from the media to civil servants, to Members of Parliament, Lords, members of the European Parliament, local people and consumers. We tried our best to build their thinking and their thoughts into the way we behaved. When we came forward we thought this would be the first such product in Europe. It is easy for us: it is our culture, but we wanted to make sure that there was choice. That was never a question. The reason we labelled our tomato puree was not for safety reasons at all. It was simply because we wanted to give information to the consumer. If you went round the stores you would find leaflets, and very well written leaflets, if I may say so, by Sainsbury and Safeway, actually explaining what biotechnology was and how it was done. That is how we approached our case. The answer is yes, our stakeholders must be involved.

75. What you have described sounds like a communication process. Do you think that consultation with stakeholders should be part of the regulatory regime?

(Dr Poole) One of the problems we have in Europe is actually working out which box you belong in. They are all equally important. Our concern at the moment is that the risk assessment system is based on very well tried, very well respected scientific principles and that is the basis of our risk assessment process. That is determining safety. Issues such as, for example, is it needed or does society want it, belong in this building at the end of the day. There are other issues which are equally important. I think biotechnology in Europe has become a lightning rod for all these other debates which are going on and I think we will need to separate risk assessment. The rule on that is to determine safety. That is advice given to a minister who then decides. Other issues are just as important and we do not decry them. They do not belong in the risk assessment process.

76. But would you see them as part of the overall regulatory process?

(Dr Poole) I believe in a democracy, yes.

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[Continued]

Lord Gisborough

77. In the event of something going wrong with a GM crop, who would be liable?

(*Dr Evans*) GM crops are no different from other crops or indeed other products. The producer would be liable.

78. The grower?

(*Dr Evans*) The producer can be defined as anything from the grower right through to the importer.

79. In your opinion do consumers accept a share of the risk and the liability if, when they purchase food, it has been labelled as containing GM material?

(*Dr Evans*) Our policy of course is to market products that are safe so in reality we do not believe that consumers think in that way and I certainly do not. Our policy is to make safe products and to ensure the excellent testing of those products. I can tell you, and I think it will not be disputed by many, that we have one of the world's best industrial toxicology laboratories based on decades of experience of course with agri-chemicals, and we also have one of the largest environmental laboratories in the United Kingdom. Our policy is to produce safe products which have passed all the regulatory hurdles, and that is our stance on this.

Lord Grantchester

80. Should labelling go further than stating that a product is genetically modified, and state the purpose of the modification, as may be the case in Canada?

(*Dr Poole*) I think we need to come back to what a label means. The label gives information. It must be verifiable and true; otherwise there is no point in having a label. I think the way you are trying to take it forward is actually giving a need. I think it is part of the communication exercise of why you are selling the product. If you looked at our tomato puree it actually says there are environmental benefits. I think it is actually best left to the producer, the company, to explain why they have done it. I do not think that should be a mandatory reason.

81. My reasoning behind this is that the consumer might beware a label saying it is genetically modified. The next question is, "In what way is it genetically modified? Is this something I wish to purchase or should I be frightened off?" or whatever the case may be, and I just wondered whether that was something that could go on the labels, "genetically modified to—" and then tell you what the reason was.

(*Dr Poole*) I think that is a very good argument and there is a lot of logic in that, but the final decision should come down in the end to the producer. I do not think that it is a role of regulation to help us sell products. We have to sell products. I would question whether or not the label is a major turn-off for people. I am sorry: we keep on talking about tomatoes but it is the only product we have got which we have experience with in Europe. We are outselling the other product. Over the two years now that that has been on the market it has sold side by side with the other product and if you look at the cans it is very clearly

labelled, "Produced from genetically modified tomatoes". I do not think it scares people. I think it is treated as giving people information and that must be right.

82. You see it more then as advertising rather than as information?

(*Dr Poole*) No, giving information is not advertising. This is giving information which I think we should do. We have not spent one penny on advertising, none of the companies has, on this product.

83. If labelling is to be required, should it be required only to the extent that the labelling can be verified by testing? What thresholds should be set?

(*Dr Poole*) I think that is a very important question. The label is so important. It has to be verified. You have got to be able to measure it in some way. Otherwise there is no point in having the label there. We, the regulators or the inspecting services will not be able to determine what it means unless you can actually measure it. I think that that is a very important area. Thresholds are also important here. We get back to the debate about understanding percentages, I suspect, and the mathematics. All through agriculture we are used to thresholds. When we sell hybrid seed, the accepted purity level of hybrid seed is, from memory, about 95 per cent for most hybrid seeds. If you take the organic label, it says that 95 per cent of the products must be organic. Those are their standards. Those are normal threshold standards which are used throughout the food industry and they have to be brought into our normal, legal regulatory system.

Lord Jopling

84. What lessons in allaying public concern have you derived from your experience of marketing the genetically modified tomato paste in the United Kingdom, and I ask this question particularly when I think public concern has been heightened by recent publicity, for instance with regard to maize modified to control corn borers and its effect on lacewings in laboratory experiments, and also the publicity which there has been about the effect on ladybirds with regard to genetically modified potatoes. All these things increase public concern but perhaps you could tell us what lessons you have learned in allaying that concern?

(*Dr Poole*) Let us take it down step by step. The most important requirement is that you have to have a product which is a good product that people want to buy. The second important requirement is to get that regulatory approval and, as we said in the written paper, one of the reasons we had to bring this product to the United Kingdom was that we had had a long history of novel food guidelines operating within this country which had been copied around the world, so you had that safety requirement. Thirdly, I think it is providing information, which is part of the label, it is showing respect for your customer, which I hope we did. Ours was the first United Kingdom product so we were setting the standards if you like. It was very important to us to actually respect the consumer, listen to the consumer, and provide that information. I think

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[Continued]

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those were the major requirements. The other point which we find it very hard to deal with is this sort of soundbite way of looking at risk assessment which is going on. An orgy of "all GM foods are dangerous". As we say in our paper, there is no such thing as a generic or universal genetically modified crop. Every species, every variety, is different. Tomatoes are very different from maize. The traits that we put into our tomatoes are very different from the traits we put into maize or soya, so each one has to be done by a case-by-case system and analysed that way, and that is a very hard fact to communicate to society. We have got to be much better at communicating the diversity of agriculture and food.

85. Surely you are more likely to get unexpected effects, and I can think of one of provoking allergy reactions for instance, following genetic modification rather than plant breeding. Surely that is right. Do you not see danger for instance in genetically modified foods provoking allergic reactions?

(Dr Evans) Yes. Allergy towards proteins, and these plants are producing proteins by and large, is a well studied subject and there are tests available in toxicology laboratories which detect these, so it is tested in that sense. The proteins are tested and indeed approved, so there is a regulatory framework which ensures this. If I may return to a partly related question when you talked about beneficials, the effect on beneficials of any crop protection treatment, whether it be chemical or genetically based, is subject to regulatory approval. It is a major part of the regulatory package. Those hundreds of environmental scientists that we employ are largely in place to deal with the environmental effects of our products and we know full well that success in the market place and success in regulation will be very largely based on the safety that we bring forward with our products, and that is why we use biotechnology, to come forward with exclusive products in terms of safety to beneficials, growers and the public. The package on safety typically will account for up to 50 per cent of the spend on a crop protection product in bringing it from invention to market.

Chairman

86. What about the danger of transplanted genes interacting with or combining with other genes to produce a toxic reaction? Is that a real danger? It certainly is suggested as such by some.

(Dr Bright) I think that is a good example where again you have to turn it into a positive question that you are asking rather than saying, "Can you show that nothing has happened anywhere?" which is trying to prove a negative. It seems to me that for each gene you have then to say, "What are the anticipated effects?" and, "Do you see those?", and in going through the laboratory, glasshouse, small-scale field trials, you then have to say, "Is this behaving in the same way as it would going through a normal breeding programme?" You will have the same scrutiny there for unexpected effects in the environment, and then, if it is a food, when you are tasting it you will be asking

questions about, "Does it taste like a tomato?", if it started out as a potato, "Does it still taste like a potato?" "Are there any other off-flavours?" and so on. Your testing process has to be there to ask questions about, "Is this still the same base? Has it still got the same hundred thousand genes that make it a tomato?" plus your one or two extra genes in there. You are always asking that against the standards, comparing it against the standards, it seems to me, rather than saying, "Is there a new interaction in general?", which is a very open-ended question to which you cannot get a satisfactory answer.

Lord Willoughby de Broke

87. Is the furthering of antibiotic resistance through genetically modified foods a genuine cause for concern? How can the least-safe practices be identified and phased out?

(Dr Poole) Again there are only a very few antibiotics which are being used in plant breeding. We have used kanamycin resistance as a marker in some of our plants. We believe that that is a safe product, and I think that has been accepted virtually all round the world now by regulators and independent scientists. However, we have to accept the fact that people are genuinely concerned about antibiotic resistance. We are therefore moving very fast away from this sort of marker, but agriculture is a slow process and it will take some time before that happens.

Lord Grantchester

88. What about the question on insect resistance? I notice in members' papers that areas are to be set aside called "refugia" areas where the crop has not been treated so that insects can survive on these crops. Am I right in thinking that sprays are never 100 per cent anyway and they only reduce insect populations? Is there a likelihood that these refugia areas could lead to insect resistance being built up?

(Dr Evans) The purpose of refugia in a crop which is expressing an insecticidal agent protein is to ensure that beneficials have a breeding ground on that crop, so it is in fact performed for the exact reason of ensuring that we do not get resistance to that particular insecticide expressed with the crop. In terms of the development of resistance to insecticide, we know that continuous pressure on the insect of the agent can cause resistance. That is true of chemicals and genes and that is a well studied phenomenon. The refugia is set there to avoid that problem. Levels of safety are built into that and in some countries of the world the percentage of refugia is quite large. As you probably know, in Australia it is a large refugia. Essentially we are doing an experiment there but it is an experiment which has got a huge safety margin. The purpose of doing that is to ensure that the effect is one to which resistance does not develop and so that effect can be used into the future.

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Lord Willoughby de Broke

89. What is the danger of genetically modified genes escaping to weed relatives and producing a superweed that presents a control problem? Can the risk be defined or quantified?

(*Dr Evans*) The concept of a superweed is very interesting and quite difficult to grasp. We have all seen *The Day of the Triffids* and I guess that can cause some alarm, but frankly I do not believe it is a problem in that farmers are used to dealing with escapes and volunteers, weeds they do not want in their crop, by using herbicides. Provided that there are enough selective herbicides on the market which kill weeds or take care of these volunteers (which is the phrase we use), that will not be a problem. Presently I can say that there are literally very many more than 10 different types of action of herbicides, so a herbicide will be available for control. In terms of the modelling of this, it has been modelled and indeed it will happen and we know the extent to which it will happen, but the control will not be the problem.

(*Dr Bright*) Can I just add to that, that the rate of outcrossing if you like between crops, weeds and feral species is different for different crops. You have to do it on a case by case basis. Genes are very unlikely to travel out from a tomato for instance because it is largely self-pollinating. Other crops have different breeding systems and the birds and bees do what they are going to do anyway in that crop. You also have to look at it case by case by what the gene is. If a gene is conferring resistance to a particular herbicide application, then that is going to have a different effect on selective advantage of weed that receives that or a plant that is left behind in the following year. If it is a different trait, if it is a trait for changing starch content, it is very unlikely to have any effect on selective advantage. It is certainly jolly difficult to become a superweed.

90. None the less the fact that there could be this outcrossing from pollination could lead potentially to a need for a farmer to have more chemicals in his armoury rather than fewer?

(*Dr Bright*) We think it is a zero sum. Again, there is a strong incentive to control that and to make sure that you have thought about that, and that is part of the regulatory assessment that goes into the release in the first place. We think it is actually quite neutral. There is always a requirement by farmers for better means of control and weeds are always evolving resistance to natural gene based resistances or chemical based resistances. It is a new example of an old problem if you like which has been going on for quite a while.

Chairman

91. Would you like to comment on Greenpeace's call to ban the planting of rapeseed because of the outcrossing dangers associated with it?

(*Dr Poole*) We are not actually involved in that area, so it is difficult for us as a company to give that comment.

Lord Grantchester

92. I detect that quite a body of opinion is to the effect that they would prefer their crops not to be sprayed rather than to be sprayed with something to survive a poison. Would you say that herbicide-tolerant crops would encourage more damaging use of herbicides in the long term?

(*Dr Evans*) I think the statement that chemicals are seen as poisons actually has to be examined. The current research in the chemical part of crop protection is dedicated towards producing superlative chemicals which are extremely safe. That is what the regulations require and that is what the companies are producing. It is possible to invent a herbicide, and I can think of two which are particularly used at the moment, which act on biochemical systems which do not hurt human beings, and these molecules have remarkably low toxicology. One of these in particular is the basis of herbicide resistance to crop technology at the moment. It does not follow that chemicals, either because of their widespread use or even because of their inherent activity, are more toxic to other species. There is no general rule in this case by case. The point I am making is that the chemicals used in that context are extremely safe, so I do not think the chemical/poison theme stands up. Our strategy as a company is to provide the farmer and grower, and indeed the stakeholder, with the optimal combination of safe chemicals and safe genetic technology. We see it as an integrated future in that context.

(*Dr Bright*) I have been involved in herbicide resistance research in terms of saying, "What can you do?", I guess for the last 15 years, and it has actually come down in the end to saying that with all this wonderful technology actually the regulation is around the herbicide. If it is a good herbicide and you can build in selectivity or change selectivity through genetics, then that is fine. If it is a bad herbicide this does not make it any better. It is really all about how we regulate the chemicals and those are very highly regulated and the hurdles are getting higher. In that sense it does not follow that you can alter selectivity either through finding a new chemical which has that selectivity or by building it in through selective breeding or through biotechnology. It is essentially about changing selectivity and that is one of the only examples. My personal preference is for spraying weeds to kill them rather than having to dig them up one by one but other people might have a different choice and as long as the choice is there it seems to me that is fine.

Baroness Young of Old Scone

93. Could I ask whether your marketing strategy is moving in the direction that some other companies have of very closely linking a genetically modified strain with a particular own brand herbicide and marketing the two as a package?

(*Dr Evans*) Certainly bundles on a crop are attractive packages to farmers and growers. It is impossible actually to tie up a whole market; there is not that amount of trust. There is always choice, and even in the cases of the bundles the farmers and

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growers have an extremely wide variety of choice in all those crops. There is one marketing strategy to provide the farmer with convenient bundles of both gene and chemical effects on particular crops.

Lord Moran

94. Can I declare an interest? My wife has a small hill-farm in Wales. As you know, the draft revision of directive 90/220 proposes that genetically modified crops should be monitored for environmental impact after commercial approval has been given. Do you think that is right and do you think it is feasible and desirable that there should be such monitoring?

(*Dr Poole*) This worries me because it is again that soundbite answer to science. This is the solution to somebody's concerns: monitor. Several times in our messages when we give them we have to come back to the science basis. The most important thing as scientists you have drummed in to you time and time again is to define the question. Monitoring is fine if the regulators can actually define a question. What are we meant to be monitoring? The hill farm in Wales: is it feasible to monitor it? Otherwise you will be spending an awful lot of money achieving nothing. There can be nothing wrong with monitoring—it is like motherhood—but you must define the question and the rationale of doing it first. For example, with certain products in America they have said they would like a review after a number of years because of this insect resistance question. That is normal practice and there is nothing difficult in doing that and our legislation does that anyway at the moment.

95. So do you think the draft revision of the directive goes too far?

(*Dr Poole*) I think it is rather badly drafted at the moment. It is sloppy drafting.

Baroness Young of Old Scone

96. Could I perhaps help Dr Poole with a question? If you were asked not only as part of the regulatory process in terms of the information you were going to provide at various testing points but also as part of the post-release monitoring process to monitor not only the impact on beneficials but also the impact on other plants and particularly the broad land use pattern that is resulting in the vicinity from changed decisions by farmers about how they manage their land, would that be reasonable or unreasonable to ask you as part of that process?

(*Dr Poole*) Again, this is not the area to go down without a scientific based question, but I think it is legitimate to ask us are we changing the beneficial insects, do we see a use pattern change in that? That is a very fair question and we would be look at that question anyway.

(*Dr Bright*) Only if you had an insect resistance—

(*Dr Poole*) I am assuming that.

(*Dr Bright*) If you had a crop where you had changed the quality for industrial use and it seems to me you would have to ask the question about

beneficials if that was one of the things that you expected to change.

(*Dr Poole*) Let us come back. It is defining the question for the crop. You then asked about land use and other take-up of the technology. I am not sure that is our responsibility. I am not quite sure how we would measure it. You are looking, as perhaps English Nature (Or is it the Government's) concern at how technology is being used. We would report how our products are used but determining the sociological aspects I think would worry me even more. That is the sort of question we would look at. You would have to define before you started the questions you examined and the answer you wanted, which is just as important.

(*Dr Evans*) One of the commonly used phrases is that association does not mean causation, so it has to be a question that is framed scientifically properly because expending our effort chasing the wrong question which is not properly defined is a waste of resources and can find totally inappropriate solutions. You have to be able to come down to define a sensible scientific question which can be scientifically answered.

Lord Moran

97. In the long run could you tell us how viable you think is the segregation of commodity crops? Could you also tell us whether you think there is a role for governments in requiring segregation or is it a matter best left to the market?

(*Dr Poole*) If you look through our research portfolio, a lot of it is into quality traits. The only way we can get value back to pay for research is segregation of those products. That is the only way that can happen. If we come to segregation of commodity crops, I believe if there is a real market pull, segregation will happen along the whole of the food chain. The agri-food chain is a very complex food chain but there has to be evidence of the real market pull for it to happen. At the moment I am not quite sure on the commodity crops but in the future we see segregation coming in as part of the normal agri-food chain.

98. What about the Government role?

(*Dr Poole*) I think in the end it has to come down to the market deciding that segregation is needed. The government role is to decide whether or not they wish to have these crops in their particular country.

(*Dr Bright*) Once they are approved then they should not have that problem; they should say, "These are now normal products" and that seems to me to be the key thing that the regulation system has to provide, to say, "Yes, these are equivalent" and if they are not equivalent then you are required that they need to be kept separate or whatever. If you are really saying they are a commodity, wheat is wheat or whatever, that probably should be the end of it. You should not be discriminating.

Chairman

99. Could I ask you a final question on which you have not had notice? Does your company take out insurance policies to protect itself against the possible

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consequences of unforeseeable consequences of genetic modification?

(Dr Evans) I cannot answer that question. I do not know the answer.

(Dr Poole) My belief is that as a company we carry our own insurance for those areas and the answer on liability which Dr Evans gave much earlier is part of that answer, but I will check with the lawyers.

(Dr Evans) We certainly have insurance policies against failures in crop and so on, so we have

insurance, but what I cannot answer is if it is specific in relation to your question.

Chairman] Thank you. The Committee is grateful to you for having come to give evidence. We have had a fairly brisk canter over quite a long haul. It may be that we have broken into a gallop at some stages. If you feel that you have not had time to answer any of these questions fully, we would welcome any amplification in written form which you wanted to send in. We are extremely grateful to you for coming and giving us your point of view on this subject. Thank you very much indeed.

Supplementary letter from Zeneca Agrochemicals and Zeneca Plant Science

I am writing with reference to the committee's request for a critique of the paper "the gaps in the regulatory oversight of biotechnology in the US", and our subsequent telephone conversation.

The legal and regulatory systems in the USA are very different from those operating in the UK or EU and we feel that an expert familiar with that system should be asked to provide a detailed comment on Dr Kinderlerer's paper. A person either from the American Embassy or perhaps Dr Giddings from the American Biotechnology Industry Organisation, (fax 001 202 857 0237).

We would, however, like to draw the committee's attention to the stated principle of the government of the USA that their primary policy is to protect the environment. In Paragraph 26 we would suggest that "in the US the authorities must *show the probability* of harm" is more accurate wording than "in the US the authorities must prove harm".

Zeneca believes that the release and use of genetically modified crops is appropriately regulated in the USA even though they use a different approach. In our written and oral evidence we make the point that in our experience for genetically modified crop plants and the food from such plants then the scientific questions asked by the US regulators are very similar to those asked in the UK or EU.

Dr N J Poole

External and Regulatory Affairs Group Manager

26 June 1998

¹ A paper by the Committee's Specialist Adviser (not printed).

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[Continued

Memorandum by Greenpeace Ltd

1. Greenpeace is an international campaigning organisation with 2.5 million supporters world-wide and 194,000 paying supporters in the UK. Greenpeace has been campaigning on environmental issues for over 25 years.

2. How we, as a society, handle the issue of genetically modified organisms (GMOs) is the best illustration of a broader question about the relationship between science, policy and the handling of risk in modern society. Food problems like BSE, pesticide residues and food poisoning all require that available science is interpreted to form policy in a way that carries conviction with the public. But what happens when the science is uncertain? In complex arenas like health and environment uncertainty is a given—there will always be uncertainty because it is almost inconceivable that research can provide all the knowledge required for certainty about the risks involved.

3. Governments have struggled with this basic truth. Official assurances of safety have unravelled as new knowledge about environmental or health impacts has overwhelmingly shown that problems are present, with the consequent loss of public confidence and faith in the systems and institutions that were meant to protect the public good. This occurred most famously with BSE, but a similar pattern played itself out with pesticide use, the effects of low levels of nuclear radiation and, longer ago, with the health impacts of smoking. One can see the same dynamic playing currently with Gulf War Syndrome and the side effects of vaccinations.

4. Genetic Engineering (GE) introduces new risks that do not come from traditional breeding methods and there are many opportunities for unpredictability to appear (see Appendix 1 by Dr Michael Antoniou, Senior Lecturer in Molecular Pathology, London).

5. This is not to say that traditional breeding methods are risk free, but GE provides new and unknown risks about which we have little experience.

6. This evidence sets out to show that the risks from genetic engineering in food and agriculture are real, and that there are major political and commercial risks being taken as a consequence.

7. Although the Select Committee is not seeking to duplicate the work of the Nuffield Committee on the ethics of genetic modification, it should be noted that many of the issues that affect food production are focused beyond that of a narrow “scientific” analysis of food content but on traceability, provenance and the process of production. A key part of retailer and food producer requirements is now that of traceability all the way back down the food chain to farm or even field of origin. For example, crop assurance schemes run by supermarkets and independent companies have been introduced, and some supermarkets are now buying beef from farmers rather than from livestock auctions. Examples of “process-led” choice available in the shops are organic production, dolphin-friendly tuna, free-range eggs, fair-trade products and an aversion to food irradiation. It is a mistake to dismiss these values as “unscientific”, indeed any scientific analysis or presentation of results will have imbedded in it value-laden assumptions.

THE RISKS FROM GENETICALLY ENGINEERED CROPS

8. Genetic engineering has produced results that can—and have—been unpredictable. Examples are documented at Appendix 2 (Too Good to Go Wrong, Greenpeace 1997) (*Not printed*) and include microbes proving to be unexpectedly resilient, the transfer of allergy by genetic engineering, unexpected pathways of escape for genetically modified bacteria and problems for genetically engineered crops when moving into real world situations. Further examples have come to light since that report was written.

9. Roundup Ready cotton produced by Monsanto and Delta Pine and Land seed company has experienced problems with the cotton bolls shrivelling up and dropping off in an effect looking similar to that in tests involving large quantities of herbicide. The problems are only associated with the Roundup Ready cotton although the mechanism is not clear¹. Sixty Mississippi farmers have considered taking legal action and Monsanto has settled out of court with most of them. Some are holding out for more than the \$100,000 offered². Reportedly, state officials say that complaints have been received from farmers in as many as seven other states³. Monsanto have explained the failure as being a result of exceptional cold weather and wrong use of varieties⁴. As Robert McCarty, Mississippi Agriculture and Commerce Department chief regulator put it to farmers “I sure couldn’t recommend they plant one of these varieties and take that kind of risk unless someone could assure them they wouldn’t have the same kind of problems we had in 1997.”⁵

10. Three hundred kilos of pulp coming from a field trial of genetically engineered sugar beet (which had not received clearance for marketing) were mixed with conventional varieties and went for processing to a sugar

¹ Kleiner, K, 1997. Monsanto’s cotton gets the Mississippi blues. *New Scientist*, 1 November 1997, p. 4.

² GenEthics News, 1998. Transgenic crop problems continue, Issue 22 February/March 1998, p. 12.

³ Myerson, A, 1997. Breeding Seeds of Discontent; cotton Growers say strain cuts yields, *New York Times*, 19 November 1997.

⁴ Colin Merritt, Technical manager, Monsanto. pers. comm.

⁵ Myerson, A, 1997, op cit.

company CSM. The pulp was traced but only after it had been incorporated into a much larger block of 12.3 million kilos of sugar¹.

11. Other reports have indicated that a number of GE crops, such as Bt cotton in Arkansas, are not producing the financial returns expected because of low yields. A Monsanto competitor has also claimed that farmers planting Roundup Ready soybeans have experienced losses of \$43 per acre².

12. Already science has shown that some risks are close at hand in terms of out-crossing of GE crops (see, for example, Appendix 3, excerpt from "Genetically engineered oil seed rape (AgrEvo/PGS) A Critical assessment and Background Information"), that small genetic changes are capable of producing significant changes in the invasive capability of plants³, and that argumentation to inform "ecological safety" is often naive⁴. Some of the proposed genetic modifications could have impacts on insects, presumably not considered in the approval process judging by the insistence by the European Commission on the authorisation of Novartis Bt maize.

13. Question marks need to be raised over the authorisation of the Novartis maize and other Bt crops by the recent work of Hillbeck *et al*⁵. Bt-maize is produced to deal with insect attack from, amongst other things, the European corn borer. Lacewing larvae (lacewings are generally considered to be beneficial predator insects) were fed on the corn borer larvae fed on the Bt maize and they survived less well than the controls. This is very alarming as Bt crops have already been authorised for growing and have been planted in France.

14. Potatoes engineered to resist aphid attack by the incorporation of a gene from a snowdrop (to produce a lectin which interferes with insect digestion) were found to have affected ladybirds. The engineered potato plants did indeed affect aphids but female ladybirds fed on aphids which had eaten from the engineered plants survived only half as long as those fed on controls. The females also laid fewer viable eggs⁶.

JUSTIFICATION OF NEW RISKS

15. Both novel foods and deliberate release need to take into account the need for justification of the risks involved. This involves answering "big picture" questions that have not been answered, either by the EU or the UK, either at a regulatory or a policy level. Examples of such questions would be:

- Is genetically modified food necessary?
- Is genetically modified food wanted?
- Is genetically modified food the right direction for long-term food policy?
- What is the justification to allow companies which wish to commercialise GM foods to expose the public to GM food risks, when the public themselves do not presently stand to benefit?
- Will herbicide-tolerant crops encourage more damaging use of herbicides in the long-term?
- Are GM crops a disincentive to investment in further research and development of (genuine) environmentally friendly agricultural practices, and is this acceptable?
- What will be the cumulative effects on natural ecosystems from introduction of many different herbicide-tolerant or pest resistant crops on a widespread scale?
- Will widespread introduction of pesticide-resistant crops have a long-term impact on biodiversity (e.g., on soil organisms, on microflora, microfauna, on flora, on birds, on other fauna)?

16. Of course many of these questions are obvious to members of the public when exposed to possible development in GE but that is all the more reason the regulatory process should not leave them out. The enquiry cannot just set these issues aside as "ethical" issues to be dealt with elsewhere.

COMMERCIAL AND FARMER RISKS

17. There are substantial commercial risks being run because of the fragile nature of public support as revealed by surveys, and particularly by focus groups which can reveal the real reasons for people's uneasiness.

18. The introduction of GMO food is coming at a time when sensitivity to food integrity and safety is high. It is also occurring at a time when the ability of political institutions to handle risks is at crisis point, and when

¹ Agarisch Dagblad (Agricultural Daily), Transgene Beet Pulp on market, 2 December 1997.

² Pesticide Action Network North America Updates Service, Disappointing Biotech Crops, April 24 1998.

³ Williamson, M, 1993. Invaders, weeds and the risk from genetically modified organisms, *Experientia*, Vol. 49(3), 1993, p. 219. The case study on *Impatiens* showing how small morphological differences can make a large impact on ecological fitness begins on p. 222.

⁴ Kareiva, P and Parker, I, 1994. Environmental risks of genetically engineered organisms and key regulatory issues, An independent report prepared for Greenpeace International.

⁵ Hilbeck, A, Baumgartner, M, Fried, P M and Bigler, F, 1998. Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae), *Environmental Entomology*, April 1998, p. 480.

⁶ Gledhill, M. and McGrath P., 1997. Call for a spin doctor, *New Scientist*, 1 November 1997, p. 4.

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people are much more likely to take definite action as a result of what they see as failures of the bodies around them. All this puts farmers and food companies in the front line in relation to any potential "backlash" when something goes wrong with a GMO product.

19. There has been much opinion polling done on GMO food including by Greenpeace. These polls generally show around 60 per cent or more of Europeans taking a negative view of GMO food, and about 20 per cent supportive. Of more significance is what underlies the general antipathy towards GM food.

20. It is clear from the Eurobarometer survey¹ that the distaste for GM food is not a matter of lack of knowledge, because the survey shows that, overall, if they know more about the issue people are not more inclined to view GE favourably. Thus the often repeated mantra that "Public Understanding" will enhance people's views towards a liking of the technology is misplaced. The Eurobarometer authors linked this to moral or value-based unease about some GE applications. Thus there is a mismatch between the regulatory framework with its intense focus on risk management, and a powerful value-based distaste for GE.

21. Further, in complex arenas like environmental or health impacts the Eurobarometer survey showed that trust acts as a functional substitute for knowledge. Levels of trust in political institutions are low. Reassurance from political actors in the event of some problem or crisis with GMO food will be ineffective.

22. The focus group research by University of Lancaster,² sponsored by Unilever was not pan-European but limited to the UK. However some of the findings are closely reflected in the Eurobarometer research outlined above. The Lancaster work provided additional knowledge on the public feelings, which show a high degree of fatalism that GMO food will arrive, despite deep and largely latent unease about the prospect.

23. Further, people would buy genetically engineered food even though they were not happy about it, showing the limitations of marketing data if it is the only means used to gather knowledge about public reactions. As consumers, people recognised that they may well purchase GM food, but would in general prefer that society were not embarking on this course, or if it were, only with a good deal more justification. This apparent contradiction has been interpreted by some to mean that people's expressed opinions in polls are not the same as their "real" views, but this would be a misguided interpretation. Labelling of GM food, although necessary (essential even) it is an inadequate response on its own.

24. Public attitudes to GMOs are complex and not easily understood. More broadly we see that UK consumers are becoming more ready to take action on the basis of inadequate service or ethical and moral concerns. Research by GGT³ in 1996 showed that 64 per cent of people said they were more likely to take action against a company than five years ago. Fifty-nine per cent believed disobeying the law could be justified in protest against something that is unjust, 14 per cent would boycott a company, three per cent would damage property as a form of protest action. How can this be reconciled with the conclusion of the Lancaster research showing apparent fatalism about GM foods? There was no fatalism about the protests over live animal exports (in the UK), road building, Brent Spar and nuclear testing by the French in the Pacific. So what is the Lancaster research telling us?

25. The answer may lie in a quote from an article written in 1995 about consumer protest: "What has driven the ordinary citizen to stop buying Shell petrol and French goods is latent anger about the power of international companies and foreign governments to do these things with such scant regard for public feeling. Nuclear testing is the lightning rod of much more than environmental concern. It is the focus of a much deeper frustration with institutions over which they have no control".⁴

26. The fatalism only converts to militant action when a "lightning rod" is provided to push people into a different mode of action. Greenpeace's own research into attitudes to environmental protest indicates that people distinguish between local-scale action where there is a sense of agency to individual action, and international issues like climate change where, generally, there is not. The global scale problems provoke an apathetic and fatalistic approach, the local scale issues (local pollution and planning issues, or shoddy service from company) a more active role.⁵ Such fatalism is understandable given that often people are put in a position of having no choice about what they want to happen—we are all in the position of having to trust regulatory processes whether we like them or not.

27. But when a "lightning rod" is provided that turns a global issue into one that can be influenced by individual (albeit collective) action, then the agency gap is bridged.

28. The same situation could apply to GM food, but what is lacking for widespread action to start is a trigger—something to identify the "lightning rod". The export of live animals through Brightlingsea had been going on for years before the protest started; once local people became aware that their action could influence things, the activities snowballed into something that local police could not control. What is awaited for the

¹ Biotechnology and the European Public Concerted Action Group, *Nature*, vol. 387, 26 June 1997, p. 845.

² Grove-White *et al*, *Uncertain World*, Food and public attitudes in Britain, University of Lancaster, March 1997.

³ GGT Research services, *Uncomplaining Brits* are turning into a nation of vigilante consumers, 28 June 1996.

⁴ Adrian Hamilton, *France learns a few pricey Pacific lessons*, *Observer*, 13 August 1995.

⁵ KSBR research on Issues and Attitudes "World Views" of the public for Greenpeace UK, unpublished.

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societal tensions in the GM food issue to find expression is a trigger, most likely for something to “go wrong”, which, as outlined above, is almost inevitable.

29. What, then will be the “lightning rod” for the public frustration? The most likely answer is that it will be the brands implicated and companies selling the products which are tarnished either by association or directly in a food health issue. Further, those farmers who are engaged in the growing of GE crops or for whom their crops will inevitably become contaminated by the crops of others will be seen as legitimate targets for public anger. With BSE it was the farmers, not the food or even animal feed companies who suffered most. Who knows where the axe will fall with a GM crisis.

APPENDIX 1

TRADITIONAL BREEDING METHODS AND GENETIC ENGINEERING: THE FUNDAMENTALS

Dr Michael Antoniou, Senior Lecturer in Molecular Pathology, London, UK

The greatest claim of those who endorse the use of genetic engineering or modification (GM) in agriculture, is that it is not only a natural extension of traditional breeding methods for the production of new varieties of crops and farm animals but it is also more precise and safer. It is said that GM:

- (i) simply gives nature a “nudge” speeding it along a pathway that it would take anyway;
- (ii) by moving a single gene between organisms, the outcomes of GM are more predictable (and therefore more precise and safer) than what occurs in traditional methods;
- (iii) in molecular chemical terms, DNA is the same in all organisms and therefore poses no great danger when genes are moved between unrelated organisms (e.g., animals to plants).

However, since technically speaking traditional breeding and GM bear no resemblance to each other, how valid are these claims? The following is a discussion which tries to address this question from a fundamental genetics viewpoint.

1. GENES AND GENETICS

Genes are discrete units of DNA which each individual inherits from its parents. Genes are the blueprints which carry the information for the tens of thousands of proteins which constitute the structures and carry out the biochemical functions of the body of any organism from bacteria to humans. Therefore, what gives each gene its own unique identity is its information content. The fact that all DNA is made of the same chemical units no matter what its source is, from a functional point of view, irrelevant. Life forms are different from one another due to differences in the information content of their genes. Variations between individuals within the population of a given species are also due to subtle differences in the genes which they all have in common.

Genetics, the study of genes, has two basic components. Firstly, there is the information content of each gene; that is, what gene carries the blueprint for which protein. Secondly, gene function or expression is extremely tightly controlled or regulated. Gene function needs to be controlled because the totality of the genetic information or DNA which is inherited, is retained in all the cells of the body. In other words, the information for the whole organism is present in every part. So, for example, the knowledge for making a kidney is present in the cells of the muscles and vice versa. This basic fact of life was perhaps most dramatically demonstrated with the recent creation of Dolly the cloned sheep. The genetic material for making Dolly was apparently derived from an adult cell from the udder of a ewe clearly showing that the genetic information for making a whole sheep was present in this cell derived from the ewe's mammary gland.

2. HIERARCHY OF GENETIC CONTROL MECHANISMS

Each gene occupies its own special place along the DNA molecule which is vital for its correct function. It is vital that the correct families of genes are switched on at the right time and within appropriate cells to ensure that the correct protein and therefore appropriate structure and function, is present in the right place, time and quantity in the body. In order to achieve this, life has evolved sets of sophisticated on-off switches to regulate the expression of genes. It would not only be wasteful but potentially disastrous for genes carrying the information for proteins needed in the liver to be switched on in the cells of the brain.

In addition, genes are now also known to be organised in distinct groups or families within the DNA in structures called “chromatin domains”. It is now clear that the expression and function of genes within a given chromatin domain are closely interdependent and that the function in one domain can influence gene functions

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within another distant domain. The function of one chromatin domain being influenced by another distantly located gene family can occur by at least two different mechanisms.

Firstly, one domain may contain genes that possess the information for a special class of proteins (called "transcription factors") that are directly involved in regulating expression of other genes; i.e., genes control the expression of other genes. If the function of these transcription factors is disturbed by a disruption of their genes, then the knock-on effect will be a disturbance in other, perhaps distantly located groups of genes whose activity is dependent on these particular transcription factors.

Secondly, the still poorly understood phenomenon known as "co-suppression" first described in plants and now also shown to occur in insect and mammalian systems, also demonstrates "action at a distance" between groups of genes that are on separate DNA molecules (chromosomes). When extra copies of a gene that is already present in a plant are introduced by GM, the expected result is that you should get an additive effect; i.e., the more copies of a given gene that you have the more of that protein you should make. However, quite unexpectedly it was discovered that in some cases this GM manipulation can cause a switching off or silencing of genes. Although originally described in plants, co-suppression type activity has now been demonstrated in GM flies and mice.

Generally, these chromatin domains are turned on and off as needed to provide an intricate, finely balanced state of gene control the complexities of which we are only just beginning to unravel. Nevertheless, tight gene control means, for example, that you will never find liver proteins and functions in your brain or leaf specific processes in the fruit and vice versa!

Nature has also evolved mechanisms whereby cross breeding can only take place between very closely related species. You can cross a cow with a cow and a sheep with a sheep but you will not have much luck crossing a cow with a sheep. The same principles apply to plants.

Clearly any technology which aims to manipulate the genetic makeup of a given organism must preserve the natural order and groupings of genes that have evolved to work together over many millions of years. This is indeed the case with traditional breeding methods where different variations of the same genes in their natural context (chromatin domains) are exchanged. This preserves tight control and complex interrelationships between genetic functions and their protein products that are vital for integrity of life.

GM: A NATURAL EXTENSION OF TRADITIONAL BREEDING METHODS?

In order to assess the validity of the claim that GM represents a natural extension of traditional breeding methods, it is important to know how GM ("transgenic") plants and animals are produced.

GM Plants

As an example, let us see how the herbicide resistant, GM soya was generated. The objective here was to introduce into the soya plants a gene from a common soil bacterium which would allow it to survive when sprayed with the herbicide Roundup. Clearly you cannot "cross" a bacterium with a plant. Therefore, the first step was to grow cells from soya bean plants on plastic dishes in the laboratory. Now, in order to allow the bacterial gene to be able to work once introduced into its new plant host, it had to be linked to a genetic switch combining parts from a cauliflower virus and petunias. (As we discussed above, the bacterial gene's own switch will only work in the bacteria from which it came). This combination of cauliflower virus, petunia and bacterial DNA was then introduced into the soya bean cells growing on the dishes in the laboratory using a procedure known as "biolistics" which employs a device called a "gene gun". In this technique, tiny spheres of gold or tungsten are coated with the DNA one wishes to introduce into the plant cells. These DNA-coated metal articles are then shot at the plant cells using the gene gun at high speed. As a result some of these metal beads enter inside the plant cells carrying the new DNA with them. Unfortunately from the point of view of the plant biotechnologist, the efficiency with which the new DNA is taken up by the soya bean cells on the dish is very low. Most of the cells don't take it up at all. So the key is to find those few cells among the many millions on the dish which have taken up the DNA. This is done by using another genetic trick. The introduction of the bacterial gene into the soya bean cells for herbicide resistance, was accompanied by a second gene which confers resistance to an antibiotic (called kanamycin). The soya bean cells were then treated with the antibiotic. The few cells which had taken up the herbicide resistance antibiotic:resistance "marker" gene combination survived and flourished whereas the majority of the cells which had not taken up these genes were simply killed by the antibiotic. Finally, by changing the conditions under which the soya bean cells are grown, the cells clump together to form what is called a callus which in turn starts to put down roots and sprout green shoots. These little "seedlings" are then potted so as to grow into fully mature plants which will carry in all their cells (including those for reproduction; i.e., pollen, etc.) the new bacterial gene. The plant which then displays the best agronomic performance, in this case resistance to herbicide, is then selected for further development (crossing to form new hybrids, etc.).

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GM Animals

The generation of transgenic animals is a no less artificial procedure. Fertilised eggs are first removed from the animal of choice. These eggs are then injected with the genes one wishes to engineer into the animal. The DNA-injected eggs are then returned to the womb of a surrogate mother where they complete their development and are born in due course.

Therefore, in marked contrast to traditional breeding methods, all transgenic plants and animals start life as individual or groups of cells growing on a plastic dish in a laboratory.

GM: A NO HOLDS BARRED TECHNOLOGY

It is evident from the procedure we just described that with GM there are no holds barred. GM allows the isolation, cutting, joining and transfer of single or multiple genes between totally unrelated organisms circumventing natural species barriers. As a result combinations of genes are produced that would never occur naturally. Transgenic crops containing genes from viruses, bacteria, animals as well as from unrelated plants have been generated. In the case of the herbicide resistant soya beans, the final outcome was the combination of genetic material from four totally unrelated organisms; a cauliflower virus, petunia, bacteria and soya. Furthermore, again as we saw in the case of the GM soya beans, the newly introduced gene units are composed of artificial combinations of genetic material. Another example which illustrates the extreme combinations of genetic material that can be produced, is the introduction of the "anti-freeze" gene from an arctic fish (the sea flounder) into tomatoes, strawberries and potatoes in the hope of producing resistance to frost. As with the bacterial gene in the soya beans, the fish anti-freeze gene is joined to the cauliflower virus genetic switch to allow it to turn on and work in its new host. (The fish genetic switch naturally only works in the fish). All this is in turn coupled to an antibiotic resistance marker gene to allow selection of the newly transformed plants.

GM DISRUPTS HOST GENE FUNCTIONS AND POSSESSES INHERENT UNPREDICTABILITY

This is clearly a great technological advance. However, the manipulation and transfer of DNA from one organism to another by GM can only be carried out with any degree of precision in lower forms of life such as bacteria and yeast although complications may arise even in these cases resulting from biochemical disturbances. The generation of transgenic plants and animals is currently an imperfect technique. Once injected into the cells of the organism, the introduced gene is randomly incorporated or spliced into the DNA of its new plant or animal host. As a result the normal order of genes within the chromatin domains is disrupted.

There is a further complication in the case of plants. As discussed already, the genetic engineering of plant cells is a very inefficient process. We saw how in order to identify the few plant cells in the laboratory culture that have permanently assimilated the new genes, the plant biotechnologist has to rely on the presence of an antibiotic marker gene. This approach is used in the production of all GM plants. As one can see this method totally depends on the function of the antibiotic resistance gene. This gene must be assimilated in a manner that will allow it to be switched on, otherwise the cells will die once treated with the antibiotic.

As we discussed above, regions of DNA (chromatin domains) can be switched off ("inactive") or expressing genes ("active") as part of vital, normal genetic control mechanisms. Since the incorporation of the new genes into the host DNA in GM technology is a random affair totally beyond the control of the genetic engineer, the antibiotic resistance gene can be incorporated into either silent or active DNA. If the antibiotic resistance gene is incorporated into silent DNA it will not be switched on and therefore the cell will die in the presence of the antibiotic. If on the other hand the antibiotic resistance gene is assimilated in active DNA, it will be switched on and the cells will survive antibiotic treatment. However, by definition, active DNA is a region where other genes are already switched on and trying to function. The random incorporation of a foreign gene into the already active domain will therefore always risk disrupting the balanced functioning of the host genes. It was previously thought that host gene functions would only be disturbed if the foreign gene spliced into the middle of another gene or into the genetic switch region which controls its expression. However, it is now known that the functions of genes within a given chromatin domain are interdependent and in many cases genes within a family grouping compete for common "master" control switches called "locus control regions". This latest model of gene organisation and function predicts that the mere presence of another gene introduced by GM into a given chromatin domain, will compete with the host genes and disrupt their balanced function. Therefore, by relying on the selection of the transformed plant cells by the function of an antibiotic resistance gene, the biotechnologist in turn selects for events where the new genes have been spliced into regions of DNA where other genes are trying to function, therefore maximising the degree of disruption to normal host gene function. This in turn maximises the degree of biochemical disturbance resulting from the disrupted gene function. Therefore, GM of animals and especially plants, always results in a loss, to a lesser or greater degree, of the tight genetic control and balanced functioning which is retained through conventional cross breeding. With GM, host genes can be silenced (rendered inactive) or inappropriately activated resulting in either a deficiency in a

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given protein(s) or the presence of the wrong protein(s) in the wrong place or in the wrong quantity or all these combined.

In addition, it is assumed that the introduced gene will behave in exactly the same way in its new host as it does in its native environment which frequently will not be the case. Gene and protein functions have evolved over millions of years to work together in any given organism. The anti-freeze gene/protein in the arctic sea flounder has evolved to work together with the other genes/proteins in this fish. It is purely an assumption that it will work in exactly the same way with no unwanted side effects in its new hosts where it will now be surrounded by plant proteins.

These effects combine to always produce a totally unpredictable disturbance in host genetic function as well as in that of the introduced gene. These phenomena which are technically called "position effects", complicate the production of every GM crop or animal. Of the several tens of individual plants or animals that will be produced with the same genes, only a few will meet the agricultural performance criteria that are being sought. This is because in each individual the foreign gene is spliced into a different location in the host DNA. Plants or animals with gross defects can always be spotted and discarded. However, subtle changes in host biochemistry that will always accompany the desired effects and which in addition to producing variable agronomic performance under different soil and climatic conditions can result in the production of novel toxins, allergens as well as adversely affecting nutritional value, are on the whole ignored by the producers of these GM organisms.

CONCLUSIONS

GM and Traditional Breeding Methods Are Worlds Apart

The proponents of the use of GM in agriculture argue that mankind has been selecting and manipulating plant and animal food stocks for millennia and that this new technology is simply the next stage in this process. However, we have seen:

- Technically speaking, GM and traditional breeding methods bear no resemblance to each other.
- GM plants and animals start out life in a laboratory culture dish.
- GM employs totally artificial units of genetic material which are introduced into plant and animal cells using chemical, mechanical or bacterial methods.
- GM always results in disruptions to the natural order of genes within the host DNA.
- GM also brings about combinations of genes that would never occur naturally.

Clearly these procedures are worlds apart when compared to cross fertilisation between closely related species.

The totally artificial nature of GM does not automatically make it dangerous. It is the imprecision in the manner by which genes are combined and the unpredictability in how the introduced gene will interact within its new environment which results in uncertainty. The balanced gene functions that have evolved together and which are preserved with traditional methods, are lost with GM.

GM VIOLATES THE BASIC PRINCIPLES OF GENETICS

Genes have evolved to exist and work in families within the context of a given species. With traditional breeding which can take place only between closely related organisms, these natural groupings of genes are preserved. Given these basic principles of life, the claim that the reductionist approach of GM, which moves one or a few genes between unrelated organisms, is a precise technology is highly questionable. What makes these assertions even more disputable, is that by selecting for the function of the foreign gene and looking only at the desired agronomic performance as an end point, GM always results in a disruption in the natural genetic order of the host. Therefore, from the standpoint of the fundamental principles of genetics and the limitations in the technology, GM is neither more precise nor a natural extension of traditional cross breeding methods. If anything the opposite would appear to be true. GM violates the laws of genetics while traditional methods work within and make the best use of the well established laws of genetics that have been laid down over millions of years of evolution.

Therefore GM foods possess new and unique safety considerations both in terms of health and to the environment. It would appear to be quite erroneous to view GM technology from purely an agriculture performance perspective upon which the current claims of precision and safety are based.

The availability of safe, sustainable, natural methods of breeding and husbandry utilising the many thousands of different varieties of any given food crop, makes the risks associated with GM foods simply not worth taking. These risks are even less acceptable when one takes into account the fact that once released into the environment, genetic mistakes/pollution cannot be contained, cleaned up or recalled like a chemical spill or a BSE epidemic but will be passed on to all future generations indefinitely.

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APPENDIX 3

THREATS TO THE ENVIRONMENT AND HEALTH POSED BY TRANSGENIC OILSEED RAPE

THREATS TO BIODIVERSITY THROUGH OUTCROSSING AND GENETIC POLLUTION

The large-scale growing of genetically engineered crops has given rise to a number of serious concerns including the effects on volunteer and feral populations and wild relatives of the crop. Genetically engineered (GE) oilseed rape is a particular threat since the crop is a member of the Brassica family, which has its centre of origin in Europe. Nine hundred species of the Brassica family can be found in Europe. This means that Europe is an important centre of diversity and there are many related plants growing in close proximity to cultivated oilseed rape. Natural biodiversity could be placed at special risk by gene flow from GE oilseed rape to wild relatives.

Local cultivars, called “land races”, and isolated populations of wild species, are particularly vulnerable to genes crossing out from new crop varieties. Gene transfers could lead to the loss or permanent alteration of these wild species or landraces. Smaller populations might literally get swamped by the incoming genes (Ellstrand 1992). Such hybridisation has been implicated in the extinction of five wild species, including the wild ancestors of maize, hemp, pepper, date palm, and sweet pea (Small 1984). Recent studies suggest that significant levels of gene flow could occur from genetically engineered oilseed rape fields following their full commercial release (Wilkinson *et al* 1995). Therefore, hybridisation is a major concern with GE oilseed rape when introduced into its centre of origin in Europe.

If the introduced gene gives a competitive advantage over other plants, for example by enabling the plant to resist diseases or habitat influences such as droughts, the gene is likely to persist and the likelihood of becoming a damaging weed in the ecosystem is increased (Ellstrand *et al* 1990). This is of particular concern with GE oilseed rape. Studies in France have shown that hybridisation occurs between oilseed rape and hoary mustard (*Hirschfeldia incana*). It was found that, under competitive conditions, these hybrid plants do better than hoary mustard (Lefol *et al.* 1995).

In addition, Danish researchers observed that hybrid plants resulting from crosses between genetically altered oilseed rape and a weedy relative (*Brassica campestris*) were highly fertile (Mikkelsen *et al* 1996). Furthermore, genetic modification may result in unintended side effects which can give a competitive advantage. For example, Monsanto's GE tomato for delayed ripening sets more seed than the unmodified parent (USDA/APHIS 1995), and the delayed softening trait in Calgene's GE tomato has conferred increased resistance to fungi which normally infect ripening fruits (Kramer *et al* 1992). AgrEvo's/PGS's GE oilseed rape contains a gene for herbicide tolerance, a gene for antibiotic resistance, a gene for male sterility and a fertility restoration gene, any

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of which has the potential to trigger unexpected side effects in the varied environmental conditions in which it will be grown.

There is also the potential that a transferred gene reduces the fitness of a native plant, leading to the eventual demise of a population. Such an effect has been implicated in the extinction of wild rice in Taiwan. The transfer of genes from cultivated rice could have made the wild rice less adapted to reproduction under varying conditions (Oka 1992). Similar concerns apply to the GE oilseed rape. The GE oilseed rape, although fertile, still carries the male sterility gene together with the fertility restoration gene. It is possible that in case of crossbreeding with another species the gene recombination could not be complete, meaning that part of the transgenes might get lost. For example, only the male sterility gene without the compensating fertility restoration gene could be transmitted, resulting in a male sterile plant which is no longer able to produce pollen. Possible negative effects such as loss of feed for pollen-feeding insects, or threatening endangered plant species by reducing their fitness, cannot be ruled out and have not been assessed.

3.1.1 Gene transfer from GE oilseed rape to related species

AgrEvo claims that the risk of cross pollination with wild relatives under natural conditions will be minimal (Rasche *et al* 1995). However, recent research suggests that the risks of cross pollination are significant. Oilseed rape is pollinated by both bees and wind. Scientists at the Scottish Crop Research Institute have shown that significantly more pollen escapes from large fields of genetically engineered oilseed rape than is predicted from earlier experiments on smaller plots. They found that escaping pollen fertilised plants up to 2.5 kilometres away (Timmons *et al* 1994).

In addition, researchers have found that gene flow occurs between fields of crops sown in the spring and autumn, and between field and experimental feral populations. They conclude that significant levels of gene flow will occur from genetically engineered oilseed rape fields following their full commercial release (Wilkinson *et al* 1995).

Studies have shown that gene dispersal from genetically engineered glufosinate resistant rapeseed to weedy species like *B. campestris* or *B. juncea* occurred under field conditions after just two generations (Frello *et al* 1995, Joergensen *et al* 1994, Mikkelsen *et al* 1996), suggesting a possible rapid spread of foreign genes from oilseed rape to its weedy (and non-weedy) relatives.

Other studies show that the release of herbicide-resistant oilseed rape can lead to spontaneous hybridisation between the crop and its weedy relatives. Research at INRA in France demonstrates that hybridisation can occur in the field between oilseed rape and wild radish (*Raphanus raphanistrum*). The progeny of the crop/weed hybrid exhibited characteristics of both parents (Darmency *et al* 1995).

Other studies in France have shown that hybridisation occurs between oilseed rape and hoary mustard (*Hirschfeldia incana*). It was found that, under competitive conditions, these hybrid plants do better than the hoary mustard (Lefol *et al* 1995). Danish researchers also observed spontaneous hybridisation between oilseed rape and another weedy relative (*Brassica campestris*) under field conditions. The hybrid plants were highly fertile and carried a transgene from the oilseed rape (Mikkelsen *et al* 1996).

Another recent French study on the gene flow from GE oilseed rape to wild radish (*Raphanus raphanistrum*), which was performed under field conditions over four generations, has shown that under natural conditions an intergeneric (between different species) gene flow might mainly occur, although slowly, by transgene introgression within the genome of the weed (Chèvre *et al* 1997).

In Germany, the Robert Koch Institute, the competent authority for authorising the marketing of glufosinate resistant oilseed rape, states that "the introgression of genes from oilseed rape into related species such as *Brassica campestris* is possible. Hybridisation of different oilseed rape lines and thus the transfer of herbicide tolerance from the genetically engineered oilseed rape line to other oilseed rape varieties is also possible." (Robert-Koch-Institute 1996)

Once transfer occurs an introduced gene may become a permanent feature of the genetic make-up of the plant, with unpredictable effects.

3.1.2 GE oilseed rape becoming established in ecosystems

Oilseed rape (*Brassica napus*) has escaped cultivation to become widespread in many parts in Europe (Sukopp *et al* 1993). Adolphi (1995) reports on a frequent incidence of the wild growth of *Brassica napus* (in Germany). Unharvested and incidentally spilled seed can give rise to huge populations of oilseed rape. In growing amongst subsequent crops in rotation, at the edges of fields or on roadside verges, it is likely to escape cultivation and become established in ecosystems in many parts in Europe. The impact this will have on the environment has no precedent and is unknown.

Once a crop escapes cultivation, it may become a permanent plant in the non-agricultural environment, with totally unpredictable effects.

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3.1.3 Conclusion

Current scientific studies and knowledge demonstrate that GE oilseed rape, when commercially released in Europe, may inevitably transfer genes to other oilseed rape and wild related species. These hybrids and the GE oilseed rape itself may become a permanent feature of ecosystems and fields. Their overall effects are unpredictable, and once these species are introduced it may take tens or even hundreds of years to recognise their effects.

EU Directive 90/220, under which the authorisation for GE rape was granted, requires that adverse effects on the environment must be prevented. The commercial growing of GE oilseed rape bears the potential for serious environmental harm. Europe is the centre of origin of oilseed rape and gene transfer from GE rape to wild species is very likely. This means the authorisation allowing large-scale release of GE oilseed rape in Europe should be withdrawn immediately. Europe should base its decision-making on the precautionary principle.

Examination of Witnesses

THE LORD MELCHETT, a Member of the House, and Executive Director of Greenpeace UK, examined and Dr DOUGLAS PARR, Campaign Centre Director, Greenpeace UK, called in and examined.

Chairman

100. Good morning, Lord Melchett. Welcome to the Committee. Thank you very much indeed for coming to give evidence to us. I do not think you need to introduce either yourself or your organisation, but perhaps you might like to introduce your colleague and then we can go straight into questions. You have kindly sent us some written evidence which arrived earlier this week together with some appendices. All Members will have received it but I am not sure that they will have had time to read every word of the appendices yet. I am sure they will in due course.

(*Lord Melchett*) My Lord Chairman, thank you very much. I am not sure if it is proper for witnesses to declare an interest but as several Members of your Lordships' Committee declared interests as farmers I should add that interest of my own as well as being Executive Director of Greenpeace in the United Kingdom. With me is Dr Douglas Parr who is our Campaign Centre Director.

Lord Gallacher

101. Lord Melchett, in relation to genetic modification, what do you object to and why?

(*Lord Melchett*) My Lord Chairman, the fundamental objection is that there are unreliable and unpredictable risks. Maybe I could expand on that a little. It is our feeling that in this area, the history of scientific advice, dealing with complex and poorly understood areas, and BSE would be an example, does not translate well into either public policy or action, or indeed into political sound bites—the need that politicians have to explain things to the public. The laboratory is much more simple than the real world and particularly the natural environment. Genetic engineering experiments have gone wrong. Genetic engineering does go wrong. There are real risks. There have been some expensive failures like the Flavr Savr tomato and there have been some recent problems which were alluded to earlier this morning like the effects on beneficial insects, lacewings and ladybirds, which have been recently identified as a potential

problem. There are clearly risks. The regulatory system, in our view, does not address those. It fails to justify those risks by asking the most fundamental questions about technology of this sort which are: "Is it justified? Do we need it? What are the alternatives?" Those are the questions that need to be answered satisfactorily in our view, before you are justified in taking the undeniable risks that you do take with a technology of this sort.

Lord Wade of Chorlton

102. Lord Melchett, before I ask my question, could I follow on from that answer. You started off by declaring an interest as a farmer and as a farmer you will know the comment that we all make, that if you have never had a dead cow you have never had any cows at all. In other words, everything that you do is a risk. Certainly all the farming activities that I have been involved in have been enormously risky, you never really knew the outcome because of the various problems. Why is the risk that is related here so different from the risk that we normally take?

(*Lord Melchett*) My Lord, first maybe I can observe that I think most beef farmers—and again I am one—would have said that one dead cow may be an acceptable risk but the scale of the problems which have affected the beef industry from feeding beef cattle, or cattle generally, dead parts of other cattle was not a justifiable risk. With the benefit of hindsight that is clearly the case. There are risks and risks, I think. Secondly, the risks of this technology are far greater than the risks we have taken in agriculture in our history, I believe. The risks involve a deliberate release to the environment of organisms which can then not be subject to control, which cannot be recalled, which will continue to exist whatever we do about it. Some of those organisms may pose significant public health risks. We may contaminate, in the public's mind, the whole of British agriculture through the use of this technology. As we say in our evidence it is our belief that at the end of the day farmers are likely to end up being blamed for this, as they have been in the public's mind for BSE, not the politicians and certainly not the

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[Continued]

[Lord Wade of Chorlton Contd]

companies like Zeneca, or in the case of BSE, the animal feed companies who were responsible for putting that stuff in animal feed in the first place.

103. If I carry on and say that in so far as your concerns are about safety does that mean you do not trust the Government's Scientific Advisory Committees? If not, why not?

(Lord Melchett) I think our answer is that our view of the Government's Advisory Committees is more complex than simply being a question of whether they are trustworthy or not. There are three points I would like to make. Firstly, it seems to us that the Advisory Committees are not asked the right questions and therefore are unable to give the answers which are necessary. So this is not a question of trust or competence. They are not asked questions like: "Is this justified? What will be the long term effects on food production and agriculture policy? Are there alternative routes which we can take? What is the need?" Those are questions which are simply not asked of any of the Government's Advisory Committees in this country, or anywhere else for that matter. That is the reason why the Advisory Committee system is certainly not adequate in our view. The second point I would make, it seems to us—and I would say this with some astonishment—that the Advisory Committees do not even seem to be asked some of the most obvious and simple questions, and the lacewing example is one. I know there is an emergency meeting of ACRE tomorrow to look at this but it seems to me incredible, given our experience with DDT and DDE in agriculture and the environment, that Advisory Committees were not asked to look at the possibility of ill effects on insects travelling up the food chain to affect, firstly, the beneficial insects like lacewings and ladybirds and so on and then, next, the species that use those insects as their prey, like many now highly endangered but previously common farmland birds, many species of which feed on lacewings in this country for example. That question was not addressed by the Advisory Committee system. Finally, to quote an American Professor of Molecular and Cell Biology at the University of California, Richard Strohman—this is looking at the degree of independence of the Advisory Committee system—he says¹ that academic biologists and corporate researchers have become indistinguishable, and special rewards have been given for collaborations between these two sectors for behaviour that used to be cited as a conflict of interest. To get independent advice in this field is near impossible in our view.

Chairman

104. You say they are not asked the right questions in your view but they are asked, are they not, to deal with safety matters including the risk of a gene escaping and so forth which are also matters which cause you some concern but in those areas nevertheless you do not think they cover these adequately, is that correct?

(Lord Melchett) Yes, my Lord.

Lord Rathcavan

105. How far are you prepared to carry your objections to these developments?

(Lord Melchett) I am happy to answer for Greenpeace. I think I should say first that the significant thing is what the public's view of these developments is and what the public do in the long run, not what any individual group or organisation and indeed commercial entity or even Government does. Greenpeace opposes all releases to the environment of genetically modified organisms. We take a wide variety of action, appearing before your Lordships' House is one of the quieter ones maybe. We take direct action against the imports of genetically modified commodity products into the European Union in a number of countries, including the physical obstruction of some imports which have turned out to be illegal. There is a large barge of, I think, maize which we stopped. The Swiss authorities then tested it. It turned out to be illegal and is somewhere in limbo between Switzerland and Rotterdam at the moment.

Chairman

106. From your written evidence, the impression I have is that you are waiting for a trigger to set off large scale public protests as happened in the case of the export of live animals. Would you describe that as being your position?

(Lord Melchett) No, my Lord Chairman. I think that would be an unduly negative position to take. Our view is that there should not be a release of these organisms to the environment, because that is a long term major risk to the environment and to public human health. We see significant signs of movement against genetically modified organisms. I should say that we do not simply represent a United Kingdom or indeed a European perspective, Greenpeace has offices in the United States, Canada, Mexico, Brazil, in a number of producer countries as well as the consuming countries like the European Union. In many parts of the world for different reasons we see resistance to this growing. What we try and highlight in our evidence, given your Lordships' particular interest in agriculture, is the real risk we think that farmers in this country and indeed elsewhere run by using this technology.

107. Your opposition to the release of GMOs, that is an absolute and definite opposition? It is not one that is dependent on further scientific research or improved procedures being developed or any satisfaction you might get with regard to the safety or otherwise in future?

(Lord Melchett) It is a permanent and definite and complete opposition based on a view that there will always be major uncertainties. It is the nature of the technology, indeed it is the nature of science, that there will not be any absolute proof. No scientist would sit before your Lordships and claim that if they were a scientist at all.

Lord Wade of Chorlton

108. Does your concern go into the therapeutic sector and to medical products produced? Are you opposed to those as well?

¹ Referring specifically to genetic engineering.

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[Continued]

[Lord Wade of Chorlton Contd]

(Lord Melchett) No, my Lord.

109. You are quite happy to produce a product using genetic engineering provided it is a product that cures people but does not feed people?

(Lord Melchett) I think that is a rather pejorative way of putting the question but we are happy to answer it.

(Dr Parr) Let me just explain our position. Our position is about the release of genetically modified organisms to the environment. The vast majority of the medical applications are contained use, as they are known, they come under Directive 90/219, a separate EC Directive. In principle we have no opposition to the contained use of genetically modified organisms.

(Lord Melchett) Maybe I can add one other point which is that the detailed investigation of public attitudes reflects this. Not primarily I think because of the difference between containment and non-containment, which is our position, but on the basis of risk, need and justification which is also a key to our position. When you ask people whether they think a particular dangerous drug which is genetically modified should be used, the answer you will get, quite reasonably in my view, is that if somebody is dying and there is a new drug which may help save their life but may, say, have a 50:50 or even an 80 per cent chance of killing them if they take it, that is fine. There you have a clear need, a clear basis for the risk and a clear benefit to the person using the genetically modified organism. That is not the case with food in our view at all.

110. Can I ask a final question. What if a genetically modified food is produced that has a particular impact upon human health, if that food is produced which is genetically modified and then indicates by taking this your risk of cancer is seriously reduced? Where would you draw the line, that is what I am trying to look at?

(Lord Melchett) Where the genetically modified organism is released into the environment and is therefore no longer containable in any way. That is where we draw the line.

Chairman] Lord Grantchester, I am not sure if your question has been covered?

Lord Grantchester

111. My question has been covered I think but following on from it is the question, if the public are made aware of all the issues, are happy to go ahead and purchase GM products, is this an area you can compromise on? Would you allow consumer choice if they are happy to purchase GM0s, knowing the risks? Are you happy to compromise?

(Lord Melchett) No, our position is that this is wrong. We should not be releasing these organisms into the environment and we should stop. Having said that, I alluded earlier to the fact that there is some significant movement taking place against genetically modified organisms in the food chain. We are delighted to see, for example, a company like Iceland Frozen Foods guaranteeing all their own label products as GMO free. Having been told for several years by

Monsanto and Cargills and everyone else apparently involved in US soya bean production that segregation is physically, commercially and every other way impossible, there are now significant moves taking place in the US to try and segregate the products so that consumers do at least have a choice. Certainly we welcome that.

Lord Willoughby de Broke

112. Lord Melchett, can I ask you, does that extend right down because we have heard the evidence from Zeneca this morning about their tomato paste which side by side with normal tomato paste outsells it and is selling very successfully with information on the tin and I gather some leaflet information available as well. The consumers are reasonably well informed and they are still buying it.

(Lord Melchett) My Lord, I listened with interest to the story of the tomato paste but, frankly, it is now an irrelevance. There was a carefully constructed British strategy to introduce genetically engineered food, to consumers, in which tomato paste was the forerunner. It has been blown out of the water by soya, maize and soon by sugar beet and, therefore, sugar. You have got to the point where 60 per cent or so of processed foods, according to the food processing industry, will contain genetically modified ingredients of one sort or another. So that careful 'take a product, put it on the shelf, explain it all in a detailed leaflet' approach is now no longer viable, and that has been lamented by some interests in the United Kingdom who wished to promote genetically engineered food in that way. It is no longer an option.

113. Nonetheless it is still being bought, is it not?

(Lord Melchett) Yes, my Lord, it is and I have no doubt that when 60 per cent, or whatever it will be, of processed food is labelled as genetically modified it will still be bought. But if you look at the attitudes of consumers in more detail you find that there is a very great underlying unease, even though people buy these products. We say in our evidence, I think, that the purchase of a product is not evidence of satisfaction with the technology, or happiness about the regulatory process, or trust in the companies or politicians who are assuring you that it is safe. You cannot equate a simple decision to buy something with all those other things. Indeed research shows that those other elements of trust and satisfaction do not exist in the general public.

Lord Gisborough

114. Are the objections exclusively environmental?

(Lord Melchett) They are environmental and human health concerns.

115. Such as?

(Lord Melchett) Maybe I should also add a concern about the future trend of agriculture in the world. The environmental dangers are well known. You have had a discussion already this morning about super weeds and the fact that Zeneca, I think, said that

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they would happen. Conventional chemicals would then be needed, we would say quite likely in greater quantities rather than lesser in the long run. The environmental threats to natural habitats and wild animals, plants and so on, are well known. There is no way of testing against the huge variety in natural ecosystems any more than there is of testing individual pesticides against the huge variety of variables in the natural world, and certainly not in combination with other conventional pesticides. Then you look at genetic modifications and the possibility of gene transfers and the effects of modifying one set of genes on other groups, families of genes in the same plant, which we have put in evidence in one of our appendices—I think it was appendix 1. This indicates that the scale of the uncertainties in this are just enormous. There are human health dangers. You talked earlier this morning about allergic reactions. It is true that if you transfer a brazil nut gene from a brazil nut to another product you will test for allergic reactions but allergic reactions are not limited, as far as we know, to those already identified. There may be many other genetic combinations which could cause allergic or indeed other ill-health in human beings, and you do not know so you cannot test for it. The problem with this technology is that it is the unexpected which will cause the problems, and by definition the unexpected are not tested for in all the systems that there are.

Lord Jopling

116. Lord Melchett, the tone of the paper which you kindly sent us implies that the cultivation of genetically modified crops will cause greater damage to the environment than existing agricultural practices. Now would you agree that really is—maybe I am wrong but if I am not wrong—the greatest presumption because is it not possible that the cultivation of genetically modified crops could improve the environment? I will give you one of dozens of examples. If, for instance, you were to get greater productivity from existing cropping patterns there would be less of a need to chop down the Rain Forest. I can think of a whole number more. Is it not a gross assumption to say the effect on the environment would be negative rather than a possibility it could be positive?

(*Lord Melchett*) My Lord, I do not think we claim the benefit of being able to know for sure what will happen in the future. What we do say is the risks we are running with this technology are greater and, therefore, the potential for disastrous consequences for human beings, or the environment, or indeed the agricultural industry are greater than risks we have run in the past. It is the nature and scale of the risks which concern us, not any certainty about actions. However, to pick up another point that you discussed earlier this morning about refugia, sacrificial areas, I think there is already emerging, it is very, very early days, some significant evidence that there will be major problems for farmers and the environment in the use of this technology. Sacrificial areas are being recommended, for example, for Bt maize of up to 50 per cent of the area planted, and that is the recommendation by

Pioneer, the seed company.¹ I think that is a pretty clear admission that there is a risk of resistance to the Bt toxin in the maize. It is going to build up extremely quickly. Even with Bt cotton the recommendation from the American EPA is for 20 per cent sacrificial areas planted with conventional crop rather than GE crop. Any farmer will know that when a new variety comes on to the approved list some stay for a long time and some disappear pretty quickly never to return. To make judgments about this within a year or two is dangerous and we do not intend to try and do so.

Lord Willoughby de Broke

117. Greenpeace have called for a moratorium on any release of GM plants. What would this achieve and in what circumstances would you end it?

(*Lord Melchett*) My Lord, actually we are calling for a ban.

118. Total ban?

(*Lord Melchett*) Yes.

119. What would this ban achieve in your view?

(*Lord Melchett*) It would avoid the risks we have talked about in terms of the threat to the environment and human health that this technology introduces. This is a completely new technology. It involves huge unknowns. It is a very crude and uncertain technology. The existence of the antibiotic resistance in GMO crops is there, as you know, because you need to find out whether the genes hit the target or not. It is presented as being the cutting edge of technology, it seems to me extraordinarily crude and the risks enormous.

120. Would you end this if you were satisfied research experiments showed they were not as dangerous as you thought at first? Would you end your ban?

(*Lord Melchett*) My Lord, knowledge changes and again I do not pretend to foresee the future so I can only answer on the basis of what we know and understand today. I believe what we know and understand today about this technology tells us that the risks will be unacceptable and inevitable.

¹ On learning of this allegation, the Pioneer Overseas Corporation supplied the Committee with the following: "In response to your call for evidence, we understand Greenpeace stated to the committee on 3rd June that Pioneer is recommending 50% refuge populations for genetically modified crops with genes from *Bacillus thuringiensis* (Bt) to confer insect resistance. This is not true, and it has never been true. We are developing Bt-maize varieties with insect resistance. We are committed to maintaining the efficacy of Bt-maize and have developed a comprehensive insect resistance management programme to ensure that Bt-maize is cultivated in a sustainable manner. The programme addresses the need for refuge populations where appropriate and it recommends either 5% untreated or 20% treated maize refuges. There has been no change to this original position." This means that Pioneer recommend that, should a farmer wish to maintain the insect population and slow down the development of Bt resistant insects, he can either grow 5 per cent non-GM seed and use no pesticide at all (As the GM maize is resistant to pests it does not need to be sprayed with a pesticide.) or grow 20 per cent non-GM seed and use a pesticide.

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[Continued]

Chairman

121. Has a ban been your policy for some time or is it a recent evolution?

(*Lord Melchett*) We have been working on this issue for just under a decade, my Lord. For just under a decade that has been our position.

122. Are there any other changes in law that you are calling for?

(*Lord Melchett*) We have recently had a meeting with the Minister for the Environment, Mr Meacher, and with a number of other environmental groups where we discussed in more detail the Deliberate Release of Genetically Modified Organisms Directive or at least the proposal for an amended Directive. There are a number of detailed proposals about how the Directive could be amended which the environmental organisations are putting together, and which we think would go some way to ensure that some of the questions which are not currently being considered by the regulatory process could be considered in the future. If your Lordships are interested to have a copy of that paper that would be possible; it has not yet been finalised.

Chairman] I am sure we would if you were able to send it to us.

Lord Grantchester

123. Just to follow Lord Willoughby de Broke's question. If genetic technology improves such that it was far more targeted and did not rely on the scatter gun application, it could be fitted in very precisely, would this advance lead you to change your views at all?

(*Lord Melchett*) My Lord, as I said, I do not pretend to be able to foresee the future but I do not think it would be right to say the scatter gun nature of putting the genes in is the only problem. We simply do not understand what impact inserting a gene into a group of genes will have on the rest of the genes in that group, still less on genes in other groups which are affected by the behaviour of the group that has had the modified gene inserted into it. Nor is there any way that I am aware of under current science of looking at how these things might develop over generations or how they might affect other species to which the gene could be transferred, particularly in the natural environment where these things are not controllable and where the potential for transfer is more or less infinite.

(*Dr Parr*) Can I just add one thing. The idea that we can do more research and elaborate and find out more is an extremely beguiling prospect. One has to look at the warping of the research agenda that can take place by simply examining one approach to agricultural improvement. A Dutch Government laboratory, TLO, have expressed concerns that by purely going down the genetic modification route then effectively, because there is a limited resource and so on, you close the door on other opportunities for developing more sustainable and more environmentally friendly technology. In a particular reference to herbicide-tolerant crops they said there may be a short term gain but in the long term I think

it is questionable as to how far this is going to take us. It is like if you want to get to the end point, which is sustainable agriculture, by purely going down the genetically modified herbicide-tolerant crops route, you are almost going down a cul-de-sac instead of finding ways forward. I think those are concerns that we would share.

Lord Moran

124. Are there any governments in the Community which are pursuing policies which seem to you right and, if so, which are those governments?

(*Lord Melchett*) My Lord, no, I do not think there are any governments which Greenpeace would say are pursuing what we believe are the right policies. Obviously there are differing views in different countries reflecting by and large, but not entirely, the differences in the extent to which public opinion is being expressed in opposition to this technology. Although I think it is worth emphasising that those differences in the expression of public opinion are underlain by concern amongst the public that in most, if not all, European countries is still very similar. I mentioned earlier the most hopeful development from our perspective seems to be taking place in the commercial world—in the market place. Whilst it is not a government, Iceland are developing, with a tremendous amount of energy and determination, their entire range of food products as guaranteed GMO free. They have shown at least that is possible, whereas they had been told by everyone, including their rivals, and all the main food companies, that it was not. Other supermarkets in this country are following behind, not going as far, but Sainsbury's to some extent and Tesco's to a slightly lesser extent. Similar commitments, although not action, have been expressed by many food retailing chains and some food producers in a number of other European countries. I think Iceland are the first to go as far as they have.

125. Could I ask a supplementary question on a slightly different aspect of it. It does seem that there is generally much more concern about this matter in Europe than there is in the United States. Why do you think that is so?

(*Lord Melchett*) I am sure there are a number of reasons. I think one clear difference is that BST, the genetically engineered product to enhance milk yields, was rejected by European farmers when companies attempted to sell it here some years ago, and in particular by British dairy farmers who wanted nothing to do with it. There was strong opposition. It was introduced in the US and, therefore, the number of genetically engineered food products, or foods that have genetically engineered organisms in them, is much greater there and has been for some time. I would not myself rely on the US consumer remaining as happy with the technology when something, as it will inevitably, goes wrong. We know from previous experience in the US that when there is a food scare there it tends to take a grip of even greater force than the food scares in Europe.

(*Dr Parr*) Can I just add something there. You have seen from our evidence, towards the end of the

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[Continued

[Lord Moran *Contd*]

evidence, we do talk about the state of public opinion in the United Kingdom and Europe. I am aware of no similar research that has been done in the US to establish what underlies consumer attitudes and approaches. If you look at some opinion polling data on, say, labelling of genetically modified foods the figures are actually very similar to those in Europe. There is a certain passivity in the US which may well be to do with other features that have come up in discussions with people, like the supportive nature that Americans have towards their home based companies like Monsanto and so on. Because we do not understand, as far as I know nobody understands, what underlies citizen views in the US, the possibility, as Peter outlined, about there being some kind of backlash has to be present.

Baroness Young of Old Scone

126. Can I ask an additional question? We have now seen fairly significant releases in a number of countries, including the US, Canada and Brazil. Are there signs of things going wrong?

(*Lord Melchett*) Yes, there are a number of instances where things have gone wrong and I will ask Dr Parr to comment on that. I would just emphasise as a farmer, to say nothing of being an environmentalist, the scale of the sacrificial areas which the companies themselves are now recommending after two or three years of use in the field does seem to me absolutely staggering. If somebody tried to market a new conventional herbicide on the basis that you could use it on half your crop and the other half you could not spray because it is going to induce herbicide resistance, they would not have much chance of selling it to many farmers. That is a clear indication of the very substantial problems of this technology.

(*Dr Parr*) I will add a few things to that. One of the features, as has already come up this morning about the scientific investigation, is if you are monitoring you have to know what you are looking for. If you are looking for something going wrong then you have to be seriously looking for it. A study by the Union of Concerned Scientists in the States dealing with the assurances of safety from field trials that have taken place there said it was not a case of showing safety, it was more a case of do not look, do not find. Secondly, I would say that if you develop an environmental problem as a result of ecosystem incursion, gene flow, or whatever, it could take place over quite a long period of time. Sometimes exotic organisms have taken over a century to get really established and start being a problem. The very short period of time that we have had so far does not demonstrate safety, it demonstrates that there has not been a problem that we have not actually been looking for. Finally, as Lord Melchett said, there have been a number of instances where things have unexpectedly—and that is the important point—gone wrong. Those range from microbes that have been released that have out-competed their parents' strain; there have been mix-ups of genes which have led to very costly seed recalls because the genes could not be tracked through the different varieties that were being

commercialised, and so on. These are outlined in Annex 2 which you may not have had a chance to look at.

127. Coming to a different issue now. There are some who are saying that unless we can get substantial use of genetically modified crops we will be unable to feed the world. How do you answer that?

(*Lord Melchett*) Firstly, I would say what evidence I am aware of indicates that the main problem we have currently in people having insufficient food is uneven income distribution, not lack of food. Genetic engineering as far as I am aware, and even the most fervent advocates have not suggested this, is not going to help redistribute income more evenly in the world so that people can afford to buy food who cannot currently afford to buy food. That is the problem that needs addressing to address starvation and malnutrition. There is no evidence that the alternatives which we would advocate, particularly organic agriculture, will be capable of feeding the world, but then there is no evidence that genetic engineered agriculture will be capable of feeding the world either. As Dr Parr said earlier we do not want to try to pretend we can predict the future, but what we do need to think more carefully about is what route we want agriculture to go down in the long run. Genetic engineering is not environmentally sustainable, it is not ecologically friendly, it is not going substantially to reduce, and it may even increase, the use of chemicals in agriculture. We think that there are real potential benefits in going down a route which is much more environmentally sustainable and environmentally friendly.

[*Baroness Young of Old Scone*] Thank you.

Lord Jopling

128. Can I ask a question on that very point? I think you quite rightly say that you think that food depends on income, there is the assumption that food depends on income, and therefore cheaper equivalent food must be advantageous to people in developing countries where income is not assured. An example which has been before the Committee in a statement made by Safeway on 29 May points out that their genetically modified tomato puree "have now been sold at 29p for 170g which compares with 29p for the equivalent of a 142g can of normal tomato puree". Therefore, that evidence seems to demonstrate that genetically modified food can be produced cheaper for the benefit of the consumer, especially in developing countries.

(*Lord Melchett*) My Lord, I do not think that canned tomato paste is going to make a major contribution to the problems of world hunger and malnourishment, nor indeed the other crops which are currently the focus of the agrochemical companies involved in this technology. Potatoes that do not go brown after they are peeled, the Flavr Savr tomato, enhancing the taste of food, the things you heard about this morning which companies are focusing on. This is frankly propaganda and it is propaganda not supported by any discernable evidence whatsoever.

129. If you were a hungry person and you had the opportunity of that propaganda, as you call it, meaning

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[Continued]

[Lord Jopling *Contd*]

that you could buy genetically modified food cheaper than you could buy ungenetically modified food, I guess that hungry person would say "Well, give me the propaganda".

(*Lord Melchett*) Yes, my Lord, it would be a guess at this stage, would it not?

(*Dr Parr*) Can I make one observation on that which is that the nature of genetically modified crops is that when applied in developing countries they are most certainly going to be more capital rather labour intensive. One of the lessons from the Green Revolution is that when that occurs you might increase your yields but you will also increase the level of hunger because you increase the inequity in particular countries. It is counter-intuitive that you increase the amount of food but you would increase the amount of hunger at the same time, but that is broadly speaking what happened. The move to genetic modification is a similar move towards capital intensive crops that are very intensive in research and development, not the sort of crops that are going to be afforded by small landholders in developing countries.

Lord Willoughby de Broke

130. You mentioned that perhaps this would not benefit the consumer in the developing world but I understand that China is the second greatest user of genetic modification. That must be some argument for saying the developing world thinks it is beneficial at the moment to try and enhance agricultural production and hence feed people better through the medium of genetic modification. Would you disagree with that?

(*Lord Melchett*) Yes, my Lord, I would. Maybe it would be useful to think of an analogy with the nuclear industry. The nuclear industry was a new technology introduced 50 years ago or so with huge promises made for the potential benefits. It was going to provide electricity for the world which would be too cheap to

meter. The nuclear industry is now, to all intents and purposes, dead in the Western World, in Europe, Western Europe and North America. There has not been a new nuclear reactor ordered in the United States for 20 or 30 years. However, the nuclear industry is still trying to push its wares in South East Asia, in countries like China and other parts of Asia. Of course it is doing so on the back of significant public, government money, provided by governments in a number of countries, Canada, France and so on. I do not think the use of an inappropriate and failed technology in a developing country is evidence that the technology has any potential benefit to the country concerned.

Chairman

131. I think that brings us to the end of our questioning. You have made the uncompromising position of Greenpeace extremely clear. We are very grateful to you for that. I dare say that you have enjoyed today one of the quieter mornings in your active life. We are extremely grateful to you for having come along and spoken to us. We would be very grateful if you were able to send along as soon as possible the other proposed amendments you have put forward to the Directive amending the release directive so that we have them to work on in subsequent sessions.

(*Lord Melchett*) My Lord, thank you very much. Thank you for your time. We would be happy to do that. I wonder if it would be possible for us to see a copy of your Specialist Adviser's paper that was referred to this morning. I think that may have some relevance to the additional points we wish to make.

132. Certainly.

(*Lord Melchett*) Thank you very much.

Chairman] Thank you very much for coming.

Supplementary letter from Greenpeace UK

With respect to the current enquiry, you were kind enough to send the paper on "Gaps in the regulatory oversight of biotechnology in the US" [*not printed*] prepared for the committee by Dr Kinderlerer,¹ and you asked for any comments. Thank you for letting us see this. While generally agreeing with Dr Kinderlerer's analysis, we do have some comments.

Probably the first point to make is that although there has been public criticism of the EU system by both US interests and the genetic engineering industry, the US system has been subject to criticism itself in the US by public interest groups (see, for example, *Peril amidst the Promise*, Union of Concerned Scientists, 1994).

Further, harmonisation of the two systems, if indeed that is desirable, should not be blind to the deficiencies of both. Neither system explicitly addresses the handling of uncertainty that is inevitably present with any new technology, especially when dealing with biological systems and ecosystems which are both complex and poorly understood. Whilst at least the EU legislation pays lip service to the "precautionary principle" the latitude with which this has been interpreted in practice—for example in the consent given to the Novartis Bt maize²—means that this is not guarantee of precaution in practice. The nature of uncertainty, and indeed factors which

¹ Specialist Adviser to the Committee.

² The Novartis Bt maize is the first genetically engineered crop to be planted in Europe. an analysis of how this crop came to be approved, how undemocratic the approval system is, how inherently not precautionary the system is, and how yawning gaps in policy were exposed by the approval process, makes interesting reading. I have enclosed a case study of the process by Greenpeace European Unit. (*Not printed*)

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are for all practical purposes unknowable, means that neither system takes as an approach "proof of safety" which Dr Kinderlerer states as being the rationale for the EU legislation in his final paragraph.

Neither of the US or EU legislative systems manage to answer the crushingly obvious (to members of the general public) questions which are required to justify these unknown risks, and some of these questions are outlined in our evidence. In summary they include:

- Do we need genetically modified foods?
- Who benefits and who has to take the risks?
- Is this the direction in which we would want to take agriculture?
- What will be their cumulative effect?

The way the current EU regulations operate is that it is taken for granted that GM crops and GM food are good things unless some specific safety problem is identified in the (industry's own) tests. All the above questions, and many others, are left unasked, and certainly unanswered.

We will shortly forward a written submission we have made to the Environment Minister, Michael Meacher about the revision of the Deliberate Release Directive 90/220.

Should you wish us to elaborate on the above please do not hesitate to let us know.

Dictated by Peter Melchett,

Executive Director, Greenpeace UK,

and signed in his absence

26 June 1998

WEDNESDAY 10 JUNE 1998

Present:

Gallacher, L.
Gisborough, L.
Grantchester, L.
Moran, L.
Rathcavan, L.
Reay, L. (Chairman)

Redesdale, L.
Wade of Chorlton, L.
Willoughby de Broke, L.
Young of Old Scone, B.
Clanwilliam, E.

Memorandum by Consumers' Association

INTRODUCTION

1. Consumers' Association (CA), publishers of *Which?*, *Health Which?* and other consumer magazines and books is an independent consumer organisation with around 750,000 members. We have closely followed the development and marketing of genetically modified foods and have included reports and updates on developments in our magazines. More recently, we published a policy report "*Gene Cuisine—a consumer agenda for genetically modified foods*" (*not printed*) which brought together our consumer research on consumer attitudes and set out our policy on controls relating to genetically modified foods.

GENERAL COMMENTS

2. Genetic modification has the potential to offer consumers benefits. This may be in terms of food that is a better quality, tastes better, or has a higher nutritional value, for example. However, genetic modification is a new technology that raises moral and ethical concerns. Although comparisons are often made with traditional plant breeding, genetic modification can take place over a much faster timescale. It also presents the possibility of gene transfer between species and this is already taking place, for example, genes from bacteria are being used in plants. Genes from fish have also been inserted into fish in order to make them withstand colder temperatures. The technology also offers the possibility of using human genes in food production.

3. In view of the progress that has already been made in a relatively short space of time, and the likelihood that genetic modification will transform our food supply, it is important to ensure that adequate safeguards are in place and that consumers can choose whether to accept or reject it as part of their diets.

SPECIFIC COMMENTS

The appropriateness and efficacy of current regulation of:

(a) *Research*

4. Much of the research relating to genetic modification has advanced before we have had the necessary debate about the direction that it should take. Genetic modification of animals is now, for example, already progressing but before there has been sufficient research into consumer acceptance. This will pose many dilemmas: for example, are genetically modified disease-resistant animals preferable to contamination with food poisoning bacteria, or is consumer concern about genetic modification and animal welfare too strong to ever make them acceptable?

(b) *Release into the environment*

5. In its 1993 Strategy for Sustainable Development, the Government stated that it would adopt "*a precautionary approach to modern biotechnology because the lack of experience meant that it was not possible to predict the risks to humans and the environment*". We strongly support this approach.

Our concerns about possible side-effects of genetic modification are set out in *Gene Cuisine* pages 20-26.

6. Release of genetically modified organisms into the environment are covered by Directive 90/220 which is currently under review. The Directive is based on a case by case approach to approval which fails to take account of the broader impact as many crops are grown and a variety of genetically modified foods are consumed. As it currently stands, there is also no provision for long-term monitoring of the health or environmental impact of genetically modified crops. We also have concerns that as the Directive is based on the principle of substantial equivalence, where a new release is assessed in relation to any existing equivalent, it does not fully acknowledge the potential for unintended and unpredictable side-effects. In addition, the

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Directive fails to provide clear guidance for risk assessment which has resulted in inconsistent risk assessment across the European Union. It is essential that comprehensive and consistent risk assessments are carried out throughout Europe to ensure that we are guaranteed the same safeguards wherever a release is given approval.

7. A recent report by the Department of the Environment, Transport and the Regions demonstrated inadequate management of releases and breaches of consent. In one case, a 400m isolation distance between a release of genetically modified oilseed rape and other oilseed rape had been reduced to 2.5m. It is essential that the conditions upon which consent is given are effectively enforced.

8. The Commission's proposed amendments to the Directive make provision for monitoring of genetically modified crops following approval with a requirement for reassessment after seven years which we welcome. However, we are concerned that great care needs to be taken if a simplified procedure for approval of some genetically modified organisms is introduced as the Commission also proposes. Whilst we appreciate that Europe needs to remain competitive within the world market, it is important to ensure that "fast track procedures" do not reduce safeguards for consumers. In the longer term, both consumers and industry could suffer as a consequence.

(c) *Novel foods and their labelling*

9. Genetically modified foods have been introduced on to the UK market before there has been agreement over labelling requirements at a European level. Prior to the introduction of the EU regulation on novel foods and novel food ingredients, approval of genetically modified foods was carried out on a voluntary basis. Since the introduction of the novel foods regulation, approval has been necessary prior to marketing which we have welcomed.

10. Our outstanding concerns relating to this approval process can be summarised as follows:

- the legislation includes no requirement for long-term monitoring of genetically modified foods, post marketing;

We are concerned that as this technology is new it needs to be closely monitored to ensure that there are not any unexpected, unintended consequences. These foods are assessed and introduced on a case-by-case basis, and the consequences of a significant number of products needs to be taken into account. As well as possible safety concerns, for example, the introduction of an allergen or a toxin, nutritional implications need to be considered as these foods will have an enormous impact on our diets.

In order to ensure that the impact of genetically modified foods and ingredients can be effectively monitored, it is essential that they can be traced throughout the food chain. If a problem were to be identified with a product post-marketing, it would be essential that it could be traced and affected products withdrawn if necessary. Our concerns about the failure to segregate genetically modified crops are discussed below.

- the legislation makes no provision for processing aids;

Genetically modified processing aids are already widely used. Although many do not remain in the final product, it is still possible that they could result in an unintended change to the product. We therefore consider that they should be included within the approval process and have welcomed the proposal in the EU Green Paper on General Principles of Food Law in the European Union that there should be European legislation to cover processing aids.

- different approaches to risk assessment can be used within different Member States and within different scientific committees;

As we emphasised in relation to the release of genetically modified organisms, there is a need for clear guidance to ensure that a consistent approach to risk assessment is adopted throughout the European Union.

One example that illustrates how different committees can reach different conclusions about the same product is the approval of the Ciba-Geigy's (now Novartis) genetically modified maize. This maize contained an antibiotic resistant marker gene. As a result, the UK's Advisory Committee on Novel Foods and Processes (ACNFP) decided that it could not approve the maize if it was used unprocessed and there was a "very low, but finite" risk of this antibiotic-resistance being passed on to bacteria in the food chain. However, the EU's expert advisory committees (Scientific Committee for Food and Scientific Committee for Animal Nutrition) approved the unprocessed maize for use within Europe, overriding the ACNFP.

This demonstrates different characterisations of risk between different Committees, and also highlights how the decision of a Committee is dependent upon the specialist advice available to it. Whilst the ACNFP has a consumer representative, this is not the case with the EU's advisory committees.

- consumers need to have greater involvement in the approval process.

Genetic modification will potentially have a huge impact on our food supply. However, this development has progressed before we have had adequate public debate about its wider consequences and acceptability. A consensus conference was held by the Science Museum in 1994, but since then developments have progressed, while many consumers still remain in the dark.

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11. Genetic modification illustrates the problems in managing risks where there is still scientific uncertainty. Products are approved on a case-by-case basis based on substantial equivalence. However, as it is increasingly acknowledged, there are limitations to our scientific knowledge and therefore we do not always know what we do not know. Although scientific advice is an essential part of decision-making, it does have limitations. As the example of the maize demonstrates, when dealing with complex, new technologies, we are often relying on expert judgment. The scientific evidence is not always sufficiently developed to be the sole basis for decisions.

12. It is essential that ways of ensuring a more socially acceptable level of risk are also explored. Interested parties, including consumers, need to be involved in the decision process as early as possible. This will help increase the robustness of the decisions that are made. It is important that the Government experiments with methods for ensuring greater public participation within the risk analysis process.

LABELLING PROVISIONS

13. The failure to provide consumers with clear, comprehensive information about genetic modification is indicative of the limitations of the current approach to assessing new technologies. Consumers were not involved sufficiently early in the process. This has meant that products arrived on the shelves and now we are trying to work out the best way to allow consumers to make an informed choice.

14. Our research which is included in *Gene Cuisine* [not printed] shows that consumers do have concerns about genetic modification and want to have clear information to enable them to make an informed choice about whether or not to accept genetically modified foods.

15. The reasons why labelling is necessary are often confused, but we consider that it is essential on the following grounds:

- labelling should not be a substitute for safety—safety of products should be assured at the approval stage;
- this is a new technology and consumers have a fundamental right to choose whether to eat food produced using genetic modification. This principle was acknowledged when irradiated foods, for example, were introduced on to the market;
- for many consumers, concerns relate to ethical and environmental issues as well as a perception that it is “not natural”. BSE has also heightened concern about potential unintended consequences of food processing; and
- in view of these fundamental concerns, consumers need to be given information that is comprehensive. Although scientists may consider that a product is “substantially equivalent” if no genetic modification can be detected at the final stage, consumers do not necessarily make this distinction.

16. Although we supported the introduction of legislation covering genetically modified foods when the novel foods regulation was agreed, and we did at last have legislation, we expressed concern about the lack of clarity of the labelling provisions.

17. The Government has acknowledged the rationale behind consumer demand for clear labelling, but unfortunately, the whole issue has been complicated by the failure to segregate genetically modified crops from standard varieties when they are harvested in the US. This has meant in the case of soya, which is widely used in approximately 60 per cent of processed foods, consumers have not had any real choice about whether or not to accept genetic modification. Whereas it would normally be left up to consumer demand to determine the use of new developments in the food chain, this has not been the case with genetically modified foods. Products have been put on to supermarket shelves whether or not there is demand. Rather than selling products on their own merits, as was the intention when Zeneca’s tomato puree was labelled and put on sale in Sainsbury’s and Safeway in February 1996, we have been given no choice with genetically modified soya and maize.

18. In light of this problem and the failure of UK supermarkets to secure segregation, a proposal for labelling of genetically modified soya and maize has been agreed by the European Union. Although progress was made in that “may contain” labelling was dropped from the proposal, it remains flawed and does not give consumers the degree of choice that our research shows they consider necessary.

- The regulation is based on the idea that you only need to label if the protein or DNA can still be detected in the final product, but test methods are still under development. The sensitivity of these methods may be improved after the legislation has been introduced and therefore they are not a firm basis for labelling requirements.
- A number of products produced from genetically modified soya and maize will not have to be labelled. This will include soya and lecithin where the DNA or protein can not be detected, and also products where processing has meant that the DNA or protein cannot be detected. But consumer demand for information is related to the use of the technology rather than whether it can be picked up by detection methods when it is sold.

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19. The only way to ensure comprehensive information about the use of this technology is to ensure traceability throughout the food chain. This means ensuring that genetically modified crops are segregated. Although this is becoming increasingly difficult with soya where it is estimated that 40 per cent of this year's US harvest will be genetically modified, it should not be ruled out particularly for other crops, including those that will be grown in Europe. Recent efforts by the UK retail sector have demonstrated that it is possible to secure non-genetically modified supplies of soya.

Traceability is not only essential to ensure choice, but also to ensure safety. If a problem is identified with a product either post-approval, or in the case of a product that has not had to go through our approval process, we need to be able to withdraw affected foods.

20. It has been argued that as genetically modified crops are increasingly grown and used in food production, cross-contamination, either as a result of gene transfer between crops or unintended contamination during transport, will be inevitable and therefore it is unrealistic to expect that there will still be products that do not contain genetically modified ingredients available. Organic food however does not use genetic modification. It is also likely that if the market does become dominated with genetically modified crops, consumers will be expected to pay a price premium for ones that are not genetically modified. This is unacceptable as in effect consumers will be paying more money for what today are considered to be standard products. Care needs to be taken to reduce and eliminate as far as possible contamination of products. There is therefore the need for careful control at all stages in the production of genetically modified foods.

21. The issue of setting tolerances has been suggested. However, consumers who want to avoid genetic modification will still want to be able to choose food that has not been produced using genetic modification. Research needs to be conducted to establish tolerances based on detection limits which ensure that consumers are provided with the most accurate information possible and enables them to make informed choices.

22. All foods or food ingredients derived using genetic modification should be clearly labelled. Processing aids are more of a problem as they are already widely used in food production. They should, therefore, be voluntarily labelled.

Approach taken by UK retailers and manufacturers:

23. In the absence of clear European legislation, retailers and manufacturers have voluntarily started to label products that contain soya or maize protein as genetically modified. They have taken the view that soya from the US is now likely to be genetically modified and therefore should be labelled as such. Whilst this increases consumer awareness about the presence of genetically modified ingredients in everyday foods, and is therefore to be welcomed, it does little for consumer choice. In the absence of segregation it is, however, the best option. Unfortunately, it does not include all genetically modified ingredients as it is limited to soya protein. It does not, for example, include soya oil and soya lecithin.

24. Whilst we have criticised using detection methods as the basis for decision-making, it is essential that resources are given to the development of validated detection methods for enforcement purposes.

THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

25. Three advisory committees have responsibility for approval of novel foods; the Advisory Committee on Releases into the Environment (ACRE), the Advisory Committee on Novel Foods and Processes (ACNFP) and the Food Advisory Committee (FAC), but we are concerned that wider issues and general issues of principle may fall between their remits. For example, segregation was not addressed by any of the committees which resulted in a failure to anticipate the action by US producers. Broader agricultural and environmental issues can also be missed when products are assessed on this case by case basis.

26. In view of concern about the environmental impact of genetically modified foods, particularly on gardeners, our magazine *Gardening Which?* recently called for the growing of genetically modified crops in the UK to be halted until we have had an inquiry to ensure that we are aware of the likely consequences and that there are adequate safeguards in place.

27. The membership and remit of the relevant advisory committees should be reviewed to ensure that issues no longer fall through any gaps in the system. Although steps have been taken to open up the advisory committees concerned, this needs to go further. Methods of actively engaging and debating future developments in biotechnology with consumers need to be developed and used as the basis for policy. We particularly welcomed the opportunity to take part in an open meeting of the ACNFP when it considered the issue of monitoring of genetically modified foods.

28. Similarly, steps should be taken to open up the relevant advisory committees within the European Union and to appoint consumer representatives. This should help to ensure that the committees start to consider the

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wider, social aspects of genetic modification. There is also an important role for the Risk Assessment Unit in DGXXIV to develop more appropriate and consistent mechanisms for risk assessment across the European Union.

THE MOST APPROPRIATE JURISDICTIONS, (INCLUDING INTERNATIONAL REGULATION AND HARMONISATION) FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

29. As foods are now traded globally, particularly in the case of commodity crops, they need to be controlled at an international level. Standards need to be set to ensure that there is comprehensive and consistent labelling of genetically modified foods. But there also needs to be international agreement over issues that go beyond national control, such as risk assessment, traceability and segregation.

30. We have several reservations about the body that has responsibility for establishing international food standards: the Codex Alimentarius Commission. Codex standards have become increasingly significant since the establishment of the World Trade Organisation. Ultimately they can decide what degree of regulation can be introduced at national or European level.

The Codex Committee on Food Labelling discussed labelling of genetically modified foods at its meeting on 25–29 May 1998, but failed to acknowledge the need for comprehensive labelling of genetically modified foods, despite our representatives, Consumers' International, calling for labelling of all foods or food ingredients derived by the use of genetic modification. Different approaches to labelling have been adopted internationally and the adoption of a Codex standard that required full, clear labelling would ensure consistency.

Broader issues relating to how Codex reaches its decisions also need to be addressed. It is currently dominated by industry and has very limited consumer involvement, although it has made a commitment to consider how this can be addressed.

THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION

31. The biotechnology industry is fiercely competitive and dominated by a few multi-national companies. It has been argued that in ensuring greater control over genetically modified foods we are losing out to US and Japanese biotechnology companies.

32. However, as we have set out above we consider that the current system still needs to be tightened. It is important not to think only in terms of short-term economic gain, and to ensure that we have adequate safeguards in place in the longer-term. Although the potential risk posed by individual products may be considered minimal, it is important to realise that many uncertainties do remain and the failure to ensure adequate control could have severe consequences for the population and the environment. Ultimately, the failure to introduce adequate systems for the approval and monitoring of genetically modified foods could mean that there will be more significant costs in the future. These could, for example, be long-term public health costs or the resulting costs of a loss of consumer confidence in food products.

June 1998

Examination of Witnesses

MISS JULIE SHEPPARD, Senior Public Affairs Officer, and MISS SUE DAVIES, Principal Policy Researcher, Consumers' Association, called in and examined.

Chairman

133. Good morning. May I welcome you to the Sub-Committee. Thank you very much indeed for having come to give evidence to us and assist us in the enquiry which we are conducting into genetic modification in agriculture with particular reference to EC regulation. Could I start by asking you to introduce yourselves?

(*Miss Davies*) I am Sue Davies and I am a Principal Policy Researcher at Consumers' Association dealing with food issues. My colleague is Julie Sheppard, who is Senior Public Affairs Officer at CA, also dealing with food issues.

Lord Gallacher

134. Miss Davies, what do you consider to be the most important implications of this technology for the consumer? On balance, does it have a real benefit or disbenefit for consumers?

(*Miss Davies*) I think it is possible that genetic modification could have benefits for the consumer. Some of the benefits that we have heard that may be possible are that foods could taste better, they could have a better nutritional content, we could be able to grow crops in areas where at the moment it is impossible to grow them, and there could also be environmental benefits. Unfortunately, the benefits that we have seen so far mainly relate to the agronomic

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MISS JULIE SHEPPARD and MISS SUE DAVIES

[Continued]

[Lord Gallacher *Contd*]

characteristics of plants and have not really had a direct impact on the consumer. The research we have done has shown that the reverse of this is that consumers have concerns that genetic modification raises ethical issues, they are concerned about the impact on the environment, and when we have done surveys people raise concerns about the fact that it might be unnatural and about what the long term consequences would be once you start to have a lot of genetically modified foods on the supermarket shelves. Overall the important thing is to give people information about genetic modification so that consumers can decide for themselves whether or not they think there is a benefit from individual products.

Lord Rathcavan

135. Miss Davies, I want to ask you what you consider to be the risks of GM crops when they are released into the environment and grown by farmers. Are you content with the way it is proposed to regulate these risks and, if not, why not? Do you think a case by case approach to risk is appropriate?

(*Miss Davies*) It is often said that genetic modification of crops is just the next stage on from traditional plant breeding as we have been doing for several generations, but the main difference with genetically modified crops is that we are talking about gene transfer over a much more rapid timescale. It is also possible to transfer genes between different species. We have already seen experimentally that it is possible to put genes from a fish for example in a plant. You can put genes from bacteria into plants. I think it is very important to be far more cautious about what we are doing, particularly as we are likely to be growing these crops on a very wide scale across the world. One of our concerns about the way they are regulated at the moment is that they are done on a case by case basis as different crops come up for approval, and there is not enough attention paid to what the overall impact is going to be on the eco system for example once you have got them being grown on a very wide scale. The way that they are checked is by field trials which, by their nature, have to be done on a fairly small timescale, and that does not really reflect what is going to happen when you are growing these crops on a wide scale throughout the country. In view of the possible implications if something did go wrong, I think it is very important to take a cautious approach to the way that they are grown.

136. Are you content with the way risks are regulated at the moment?

(*Miss Davies*) One of our concerns is that with Directive 90/220 which covers the approval there is not any requirement for long term monitoring of crops. The Commission's proposal for a revision to 90/220 suggests that there will be this seven year period during which there will be monitoring and after which the approval will have to be reconsidered, and that is something that we definitely support. The other problem is that there has been inconsistent risk assessment across the European Union where different advisory committees take different approaches to

genetically modified crops. The example of this was with the Bt corn, which had the antibiotic resistant marker gene in it, where you had the Advisory Committee on Novel Foods and Processes here in the United Kingdom deciding that it presented a low but possible risk and that it should not be approved if it was not processed, whereas you then get the European committees considering it and, based on the same evidence, they come to a different conclusion. It is important therefore that we establish consistent methods of risk assessment so that we are guaranteed the same safeguards wherever these crops are going to be approved.

Chairman

137. You call for monitoring in your paper "Gene Cuisine", which you kindly sent. Could you say something about what that monitoring should be for? You refer in your document to the possible impact on diet. You refer to the need to discover more about the build-up of antibiotic resistance. What specifically and how many goals should there be in monitoring and on whom should the burden of monitoring be placed?

(*Miss Sheppard*) Obviously monitoring is critically important given that the field trials are themselves a limited indicator of what might be a potential risk. What should be monitored, why it should be monitored and how it should be monitored I think is a matter for public debate which has not yet been had. I know that Jeff Rooker, the Food Safety Minister, has already committed himself to further work on monitoring. They have already set up a working group as part of the ACNFP to look at the difficulties of monitoring genetically modified ingredients once they are in the food chain. That was thrown open to the public and I went along as an observer. One of the things that was very obvious from the discussions was how difficult this problem is going to be, especially with, say, genetically modified commodity crops which have not been segregated, which are very difficult to trace throughout the food chain. The question of how can you monitor what cannot be traced is extraordinarily difficult. Also, when you are dealing with a commodity ingredient these are often used in very small quantities but they are used across a very wide range of foodstuffs. How will that practically be done? From the discussions that I heard amongst the experts there, it was clear that this was going to prove to be a very intractable problem. I think the implication of that is not that we should not try and monitor but, given the difficulties that we are going to encounter with that, maybe we need to look again at the regulatory approval process to make sure that that is as robust as we can make it simply because downstream we are going to have all these enormously difficult problems to deal with.

Lord Wade of Chorlton

138. Just before I ask my questions, could I follow on with a point that my Lord Chairman has raised on monitoring. Surely you can only monitor that which is measurable and you cannot manage something which you do not measure.

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MISS JULIE SHEPPARD and MISS SUE DAVIES

[Continued]

[Lord Wade of Chorlton *Contd*]

(Miss Sheppard) Sure.

139. Or the other way round, which is the point you are making. But surely the Consumers' Association need to have a view on what are those issues in genetically modified foods that are giving cause for concern to consumers so that you can start and focus on to those issues that might need monitoring. Surely that is an issue that you will have to address, is it not, because if there is a public debate the Consumers' Association is an organisation which has a view on it.

(Miss Sheppard) Certainly it is a whole area that we are going to have to address. Clearly we are as concerned as everybody else about for example the creation of allergies or new toxins. I listened to a roomful of assembled experts drawn from many different disciplines and they were finding it extremely difficult to identify precisely what should be monitored and how it could be monitored. I think we do need to have a public debate but we also need to have better expertise available so that we are able to address that problem but yes, clearly, we are going to be very active in that debate when it happens.

140. Could I now move on to my questions but first of all may I declare that I do have an interest as a farmer and I am in the food industry but I do not deal with GM products. As you said in answer to Lord Gallacher's question, you appreciate that consumers in the United Kingdom have concerns over GM foods, although these are not easy to define or measure. From evidence that we have received it is suggested that this is partly due to the BSE and other food scares that have been concerning the public and have been very much in the public eye over recent years. How do you feel that these consumer concerns should be dealt with?

(Miss Sheppard) I think you are right to pinpoint that there has been a breakdown in public confidence over the way in which we manage food risks and that, as you rightly say, is probably related to, latterly, BSE but also other food scares that we have witnessed over the last decade. It is certainly true that because of that consumers are probably no longer willing to accept blanket assertions of safety either from experts or politicians. We are hoping that the new Food Standards Agency will help address the problem of restoring public confidence in the way in which we control food risks. It is going to take a number of years before that is in place and in the meantime the technology is developing at a fairly rapid pace and there are other things that we could possibly do in the interim. If we think about how risks are communicated more generally to the public, it is certainly the case that in the past expertise has not been very willing to acknowledge the uncertainties and incompleteness of scientific knowledge and I think that is one of the things that needs to be done in order to address public confidence. Notwithstanding that, I think we need to acknowledge that even when consumers have the best possible and fullest information available to them, they still take the view that the risks associated with this technology are not acceptable to them. Whether or not you and I agree with these if you like ethical reasons

for rejecting or feeling sceptical about the technology, I think it is something that we need to take into account. It is going to be very important that consumers are given the choice about whether they consume genetically modified foods or not, and that implies segregation, traceability and proper labelling. We need to have a proper public debate. Our research has suggested that in fact people's attitudes to different applications of genetic modification can be very different. People who feel relatively relaxed about plant biotechnology may not feel the same way about, say, the genetic modification of animals. There is if you like a spectrum of opinion even within one individual. In a sense our regulatory framework is not sensitive enough to those kinds of gradations, those nuances, in opinion towards genetic modification. The reason why we are seeing so much controversy over genetic modification at the moment is that the technology if you like has run apace of public acceptance and we do need to have a public debate about what direction the technology ought to go in or indeed whether it ought to be applied or not and in what areas. For the future, what we can learn from the current controversy which is being played out in the media is that we need to have some kind of mechanism whereby we have the public debate before the stuff hits the supermarket shelves. In a sense what we are seeing now is a debate that should have happened nearly 10 years ago.

141. You are the Consumers' Association so I assume from that that you will have a better understanding of how consumers feel on the quality of food. Putting GM to one side for a moment, what is your view on the quality of food that is now offered to British consumers? Is it actually worse than it was? Are there specific problems, or would you agree with me that possibly the quality of British food that is now offered to consumers is probably as high as it has ever been?

(Miss Davies) As you say, there is some very good quality food around and we are starting to develop mechanisms like hazard analysis to make sure that we are increasing controls at all stages throughout the food chain. We have had a lot of problems with the food chain: cases of food poisoning for example which, for some reason which nobody knows, continue to rise, so there are a lot of problems at the same time that you really do need to tackle. As you say, I think this has made people concerned about new technologies and the pace of change that can take place before we are sure about what all the possible implications could be.

Lord Moran

142. In relation to what you said just now, is it your impression that consumers in this country are more concerned about genetic modification in animals and fish than they are about modification of plants?

(Miss Sheppard) Certainly our research seems to bear that out and that seems to be duplicated in other research that we have seen on consumer attitudes towards different applications, yes.

(Miss Davies) One of the interesting things that we are going to have to debate is where consumers would

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MISS JULIE SHEPPARD and MISS SUE DAVIES

[Continued]

[Lord Moran *Contd*]

actually find genetic modification of animals acceptable, if they would at all. There is research already under way, for example looking at making animals resistant to disease and so we need to have a debate about whether having animals that have a lower instance of *E.coli* or *campylobacter* is going to make genetic modification of animals acceptable to some consumers. As Miss Sheppard pointed out, we need to have that debate before suddenly, in three or four years' time, we have actually got meat on sale in supermarkets and find out that it has been produced using genetic modification.

Baroness Young of Old Scone

143. The two regulatory committees, ACRE and the Advisory Committee on Novel Foods and Processes, are really, in terms of their remit, primarily concerned with safety issues. Do you think that there should be some forum for the resolution of some of these wider issues, for example the role of GM crops in agriculture and the environmental aspects?

(Miss Davies) Yes, definitely, because, as you say, there are the two committees that deal with genetically modified foods as well as the Food Advisory Committee that does have a role. They have very specific technical remits. Some of these broader issues about what the overall effect is going to be on the eco-system, for example; what impact it is going to have on the use of chemicals in agriculture, and also the practical issues, such as how do we actually trace these products? how do we ensure segregation? have been missed while we have been focusing on this case by case approach. We definitely need some body that is going to look at the wider issues, particularly as we get a lot of products coming on to the market.

(Miss Sheppard) Could I add that because the regulatory process is not allowed to address, if you like, these big picture questions, that in fact fuels the controversy out there in the world, in the media. If those big questions that are concerning the public are not addressed inside the system, then they can only be addressed outside the system and I do not think that is very helpful.

Chairman

144. Do you have any ideas as to how this should be addressed? Would you like to change the remit of the existing advisory committees or establish a new advisory committee? If so, how would that tie into the existing ones and into the whole regulatory process?

(Miss Sheppard) One of the things that we have already suggested to the Food Safety Minister is that there needs to be some kind of co-ordinating committee that tries to pick up these big picture questions that at present fall through the gaps in the system. Obviously we are not too keen on setting up more layers of bureaucracy but we do think that there is a really clear role for some kind of co-ordinating body that can pick up these questions.

Baroness Young of Old Scone

145. You were very clear that, because of the difficulties in monitoring, regulation needed to be fairly rigorous as a first stage. Are there any thoughts you have, either on the regulatory or monitoring process, in respect of these broader environmental issues and broader agricultural issues?

(Miss Sheppard) For example, it is not part of ACRE's remit to look at, say, the impact of GM crops on the use of broad spectrum herbicides. It is not within the remit of, say, ACFNP to address questions relating to the need for traceability through the food system. These are all absolutely critical questions and these are the questions that have if you like fuelled public controversy. It would be far better, as I said before, if these were addressed inside the regulatory system rather than only outside.

Lord Gisborough

146. Should public participation in the regulatory process be improved?

(Miss Sheppard) I do not think it will be any surprise to you to be told that our answer is yes. Because of the public anxieties that are surrounding this technology we think that the Government needs to increase public participation in the form of consumer representation on the relevant advisory committees, but also be much more proactive about soliciting public views and opinions on developments and proposals that they have got in train. There are lots of different devices for doing that. We always draw a distinction between consumer representation and soliciting views from consumers. The role of a consumer representative is to represent the consumer interest. That is not the same thing as soliciting views from consumers. There are two parallel systems running here. I think we need to strengthen both. I suppose we need to ask what consumer representation is for. We think there are several advantages in improving the role of consumers on these committees. Consumers very often ask the kinds of questions that simply have not occurred to the experts, the flat-footed, obvious question that might occur to you and me about, "How are we going to monitor this?" may simply not occur to some of the experts who were locked into very detailed discussions of the finer points of genetic modification. I also think that increasing the role of the consumer on committees improves the openness and transparency of the process. It is really important in terms of restoring public confidence in the system that consumers do not feel that these are decisions that are being made behind closed doors to which they do not have access. Obviously we are aware that although our national advisory committees do give advice and take decisions and make recommendations, increasingly these decisions are being taken by international regulatory bodies. At the moment there is no consumer representation on EU scientific advisory committees as we have in the United Kingdom. We think that this has got to be addressed with some urgency. It seems to us there can be no valid reason for excluding consumers at a

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[Continued]

[Lord Gisborough *Contd*]

European level when we happily include them on United Kingdom committees. Here in the United Kingdom we have had a good experience of doing that. We think that ought to be addressed at EU level but also in organisations like Codex where very important decisions are taken about, say, labelling which again has very inadequate consumer representation and that also needs to be addressed.

Lord Wade of Chorlton

147. The traditional way to test consumer reaction has been the market place. Do you think that the way in which things are changing that is no longer the way to deal with new products coming on to the market? Do you think that if we set up small consumer groups to test something, if we had done it 100 years ago Mr Ford would have made the first motor car? When producers put a product into the market place it is a risk. The consumer may not like it and out of the new products that are put into the market place the vast majority fail because the consumer does not like them for some reason or another. Do you now feel that the time has come to re-look at that traditional system for testing consumer products?

(*Miss Sheppard*) The market has always been a very fallible instrument for telling us what consumers want and do not want. Particularly in relation to genetic modification it is fatally flawed. The distortions in the international commodity market are such that market forces do not operate very freely. I do not think anybody would claim that we have got a market mechanism for ensuring that consumers who want to eat genetically modified ingredients or do not want to can effectively articulate that through the market. I think the market is a very imperfect instrument in relation to genetic modification and we do have look at other mechanisms that we might use.

Lord Redesdale

148. You said earlier that this is a debate that should have taken place 10 years ago and there seems to be a large pressure building up in the press over the risks that genetically modified food are producing. Do you think that is going to have an irrational reaction from the public or do you actually think that they are going to accept genetically modified food because it is already there on the supermarket shelves or could you see a point at which this movement would build up such a head of steam that there would actually be outright rejection of genetically modified food

(*Miss Sheppard*) It is not surprising that consumers get concerned about new technology, particularly when it appears to be moving quite quickly. We have found that consumers have very different attitudes towards food than they do say towards a new washing machines or new vacuum cleaners. It is a very personal thing; it is something that you experience every day. It is, or was at one time, at the threshold of family life. It is a very sensitive barometer of how people are feeling. It is also true that consumers are much less likely to be reassured by experts saying that something is perfectly safe and

even less by politicians saying it. I think that as a society there are social changes going on which are making us feel more socially insecure: job insecurities, family breakdown, all these sorts of things. I think that means that probably we are more preoccupied with risk than we once used to be because we do not feel quite so much in control of our lives as we used to be. I think there are very legitimate concerns about genetic modification and I think that the sorts of worries that we have seen are not irrational but rather a rational response to some of the bigger changes that are taking place in society, certainly to some of the failures that we have seen in risk management over the last decade. It is not helped when there is a perception that genetically modified food has been foisted on to the market without adequate discussion or without making provisions for adequate choice or labelling. Nevertheless, no matter what you or I might think, there are always going to be people who feel utterly opposed to this technology on ethical grounds. I think that has to be respected. It may well be that had genetically modified soya been introduced rather more sensitively than it was, we might not have seen the whole criticism that has followed in its train but we need to recognise that there will be some people who are always going to be opposed to it.

Lord Grantchester

149. There are other technologies, like BST (Bovine Somatotrophin) that have come onto the market, and the farmers or consumers have resisted them to the extent that the issue has gone away. Do you see that genetic modification could be such an issue that might go away if people voiced their concerns strongly enough for long enough?

(*Miss Davies*) In the case of BST I do not think it has quite gone away yet because there is a moratorium at the moment until the year 2000 and it is an issue that is being considered within Codex Alimentarius and they have put off their decision until September when they have a meeting to decide what issues should be considered in relation to approval of BST. I think the pace of development of genetic modification means that it is here but without consumers being able to decide and make a choice for themselves it is going to be very difficult, as we mentioned before, for the market to decide to what extent we have it. In the case of soya, it is already in 60 per cent of products without us really having any choice about it. I think the reverse of that is that before we do start to have all of these crops coming on to the market, if we do put in the proper controls now and make sure that consumers do have a choice and make sure that crops can be segregated and traced, then at least we can determine the extent to which it does have an effect on our diet.

Lord Willoughby de Broke

150. In your opinion do consumers accept a risk and a liability in purchasing and consuming food if the label says "genetically modified"?

(*Miss Davies*) I think it is important to separate out labelling and safety because when we have called

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[Continued

[Lord Willoughby de Broke Contd]

for labelling of genetically modified foods we do not call for labelling on the grounds of safety. We think it is important that safety is addressed by the approval process and that when foods go on sale they are as safe as they possibly can be. We acknowledge that there is no such thing as a completely safe food and even with some of the traditional products that have been on sale there is always going to be a slight element of risk, but this is a new technology and it is happening at such a rapid pace that if anything should go wrong it would affect such a wide number of products and some of the changes could be irreversible. That is why it is so important to be cautious at this stage before we suddenly proceed even further with the technology. Labelling is really to do with making sure that consumers who do have ethical objections, or who are concerned about possible environmental effects, can choose whether or not they want to eat genetically modified foods. The safety aspects and the risk need to be addressed by the approval process and, as we have already mentioned, we think that could be tightened up to make sure that the risk they are taking is minimised further.

Lord Moran

151. You have just mentioned the question of labelling. I wondered whether you were happy with the latest Council agreement on labelling. Do you think it is adequate, from the point of view of the consumer, if labelling simply says that the product is genetically modified or contains genetically modified material, or do you think it should go further and give on the label the purpose of the modification, as I believe is the case in Canada at the moment?

(*Miss Davies*) In relation to the Council's agreement, we do not think the regulation does go as far as we would like it to. Our main concern is that it is based on whether or not you can detect DNA or protein in the final product. The first concern that we have is that at the moment the detection methods are not that advanced so they are likely to be developed further and become more sensitive, so it is not really a firm basis for the labelling requirements. It also means that a lot of products are still not going to be labelled. In the case of soya, genetically modified soya lecithin and soya oil are used in a wide range of products, and the research we have done suggests that consumers are concerned about genetic modification and want to know about whether genetic modification has been used, not necessarily whether it is there in the end product or whether it has been processed out before the final product goes on sale. The research that we have done asking people what they want from labelling shows that they want the labelling to be up front, they want it to be on the front of the packet to indicate whether or not it does include genetically modified ingredients. One of the interesting things that came out as well was that people felt quite strongly that there should be a symbol that could go on genetically modified foods so that they could easily identify whether or not something was genetically modified. That goes back to the issue of standardisation as well, so that when you are shopping in a hurry you know

what you are looking at and it is on the front of the packet. Ideally we would like products to say how they have been genetically modified and hopefully that will happen. With the Zeneca tomato puree that has been on sale in Safeway and Sainsbury's they did do that. They put a little paragraph on the side of it to say how it had been modified but I think we have to acknowledge that as more products come on sale you could have a product that is going to have a wide range of genetically modified ingredients and so it might be impractical to give that kind of information for all the ingredients. I suppose the best option there would be to make sure that you have leaflets at point of sale so that consumers can find out more about it and that would have to be next to the product because quite often we have found that leaflets are provided but you do have to hunt quite hard for them in the supermarket or even phone up if you want to get a copy rather than just being able to pick it up while you are shopping. More generally, I think labelling needs to be backed up by clear information so that when consumers are choosing, they are really making an informed choice and that is going to be a crucial role for the Food Standards Agency: to make sure that consumers are given advice and information about genetically modified food so that they can decide for themselves whether or not they think there is a benefit.

152. You mentioned soya which has obviously been used in a great many products. I wondered if you thought it was going to be practical to have effective labelling to give consumers a choice, given the fact that something like soya is used in a huge range of products.

(*Miss Davies*) Soya has obviously caused a lot of problems and has been very difficult but we still think that segregation is possible. Some of the actions recently by some of the retailers has shown that it can be possible to find non-genetically modified varieties of soya and give consumers a choice about whether or not to accept it. What the retailers and manufacturers have decided to do, which we did welcome, was, in the case of commodity crops where they could not be absolutely sure whether or not something was genetically modified, to label it as genetically modified. That alerts people to the fact that they are buying genetically modified food but unfortunately, if you do have that kind of blanket labelling, at the end of the day you do not really have any choice. You know you are eating it but unless you want to avoid that type of product completely and cut out soya from your diet, then you are not going to have a choice. That is why at the end of the day it still comes down to segregation, although it has been difficult with soya, I think it is important not to give up as other crops are grown in Europe and come onto the market, and just assume that we cannot have segregation. We need to consider that early on when they are being approved to make sure that they are segregated as they are grown so that we can make an informed choice.

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[Continued

Chairman

153. You mentioned that consumers want to know whether the process of genetic modification has been used in producing the product, not simply whether there is DNA present in the product, which is in principle testable, but whether or not the process has been used, which is often not testable, so how would you propose to make that a legal requirement that the label should say whether or not the process has been used? How could you test for that?

(Miss Davies) I think it has to come down to traceability throughout the food chain so that producers and retailers make sure that they know where they are getting their ingredients from. Traceability and segregation are not just going to be important on the grounds of consumer choice. As Miss Sheppard mentioned before, it is going to be important for safety reasons because if we ever found that there was a problem, for example if a product had been approved in another country that did not come up to the same standards as we would have here, we need to be able to recall that product if there ever was a safety problem. So we need to work out ways of ensuring better traceability all the way through the food chain.

(Miss Sheppard) There are already precedents for this in other areas of food labelling like free range, organic and so on, which are all based if you like on an audit trail and traceability. There are precedents there and we know it can work.

154. You can operate it within your own country. It must be more difficult in large internationally traded commodity crops, must it not?

(Miss Sheppard) Certainly soya has presented a very formidable challenge to all of us in terms of thinking through some of these problems, which is why really we need some mechanism for talking about these developments before they happen. We were equally guilty for not seeing these difficulties, whereas we should have had some kind of regulatory system in place that could anticipate the likely questions that are going to be raised for some things in train.

Lord Grantchester

155. I have seen it reported that the public acceptability of genetically modified food is partly dependent on whom they perceive benefits from the technology, whether it is done for their benefit or the farmers' benefit or the manufacturers' benefit. Do you think this is an important consideration to be borne in mind, bearing in mind that there might be implications for labelling? Do you think this is important for a public perception?

(Miss Sheppard) Yes. In terms of public perception we all make if you like our own amateur judgements about risk assessment, balancing risk against benefit whenever we make a purchase. Probably even very small risks are less acceptable to us as individuals if we perceive no benefit from that particular development. It does happen that this first wave of applications of genetic modification do not appear to have any tangible benefit for consumers. I think it is a great pity that although the technology may benefit growers they in turn need to think how

that will impact on their customers, the final consumer. I am sorry: what was your question again?

156. With many modifications, the consumer will benefit but apparently indirectly, because if the crop is grown more cheaply it will produce cheaper food. My question was on how the public perceives genetic modification, ie is it for their benefit or is it for the farmer's benefit? Is that an important reason for the acceptability of genetic modification? Is that one of the reasons why it is categorised in certain ways, either for or against, rather than a blanket against the whole concept of genetic modification? My perception is that the public does have different perceptions. I am asking you to confirm whether your continued association with research reveals any trends for why genetically modified food is either looked at in a good light or a bad light. And, if it is true that it is looked at in different lights as to who benefits, whether that has any implications for labelling, for example, to say why something has been modified, so that the consumer can then make a choice, "I do not like that because it is not for my benefit" or, "I do like that because I can perceive that as to my advantage."

(Miss Davies) Our research does confirm what you say. When we asked consumers who they thought benefited most from biotechnology—and this is a survey that we did in May 1996—only seven per cent of consumers thought that they benefited most from genetic modification, whereas 47 per cent thought that the industry, whether it was manufacturers, retailers or farmers, benefited the most from biotechnology. I think it comes down again to giving consumers clear information about how products have been genetically modified so that they can make their own decisions about whether or not they think that there is a benefit for them and whether they think the benefits outweigh the risks.

Chairman

157. We were told that the genetically modified tomato puree that sells in this country in some supermarkets sells at a price 20 per cent cheaper than the unmodified tomato puree. Do you not consider that to be a consumer benefit?

(Miss Davies) Yes, it does seem to be a benefit but when we did our research we asked consumers whether price would have an influence on their decision to purchase, and it showed that price did not really seem to affect their decision about whether or not to accept genetic modification. They did say that they wanted more information about genetic modification so that they could be making more informed decisions when they were choosing whether or not to buy them.

Lord Redesdale

158. You mentioned a survey and you have a graph on page 10 of your *Gene Cuisine* paper which seems to suggest that most categories said that under 40 per cent benefited and more than 50 per cent did not benefit. So most people considered that more than 50 per cent of consumers are not going to benefit from the changes.

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[Continued

[Lord Redesdale Contd]

(Miss Davies) Yes. Some people did not respond but overall it showed that most people thought that it would be the industry that would benefit rather than themselves. Some of them did see some benefits and I think they are mentioned there as well. The sorts of benefits that they mentioned were that food might taste better.

Lord Wade of Chorlton

159. How many members of your organisation are there and when you send out these surveys how many people do you actually invite to comment and what proportion come back with any views?

(Miss Davies) We actually have around 750,000 members, but when we do surveys we do not usually

survey our own members because they tend to be slightly more informed than some consumers. We make sure that we do a representative sample that reflects the population as a whole. We have got our own survey centre which sorts out the sampling plan and decide which areas we need to go to. When we did the survey in May 1996 that I mentioned, we went to four areas around the country and we did face to face interviews with just over 500 people.

Chairman] That brings us to the end of the questions that we had to put to you. We are extremely grateful to you both for having come before the Committee and answering all our questions fully and freely and for the excellent written material you sent us. Thank you very much indeed.

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Memorandum by Iceland Group plc

INTRODUCTION

Iceland Frozen Foods Plc is 28 years old, comprises primarily a retail operation with 770 stores, 20,000 staff and a turnover of £1.7 billion. Iceland is a frozen food specialist but also offers a wide range of both chilled and ambient products.

1 SUMMARY

Genetic modification clearly can provide significant benefits for society but also has associated risks and raises a wide range of issues for consumers.

We believe that the introduction of GM commodity crops is a significant departure from traditional breeding methods. We share the concerns raised by several independent scientists regarding the way in which these products are being brought to market.

We believe customers need to be informed as to what is going on and need to be given a choice as to whether or not they buy GM products. As a result we have been raising the profile of this issue.

We believe that many of the advisory bodies at EU and UK level had a strong bias towards bringing this technology to market. We have been working to ensure that consumer concerns are addressed within the process. Progress is being made but there is still some way to go.

2 APPROPRIATENESS AND EFFICACY OF EU AND UK REGULATIONS

As a food retailer we have had to spend a great deal of effort of late ensuring that regulations are effective, clear, practical to implement, allow innovation and minimise the disruption and cost to the trade.

The difficulty in achieving consistent regulation across the EU often leads to prescriptive regulations that are inflexible and difficult to apply in parts of the community. The complexity and wide range of food operations lead enforcement agencies generally to prefer end point testing and prescriptive checklists. Operators on the other hand generally prefer risk assessment and in-process controls. This latter approach provides the flexibility to develop new solutions to the issues with compliance that face their specific operation.

We believe that often the best solutions arise from co-operative ventures that involve all interested parties at an early stage.

(a) *Introduction of GM Commodity Crops*

Unfortunately with the introduction of genetically modified (GM) commodity crops the biotech industry and those responsible for legislation were unwilling to listen to, or act on, the concerns raised by retailers and customers within the UK and across Europe.

We believe this is because there was a general feeling that the profit to be made was so great that no country could afford to be left behind and no-one believed there would be any point in standing up to the might of the large conglomerates that operate in this sector. As a result Governments have invested heavily in research in this area and are in fact very closely aligned to the biotech industry. The significance of this industry is such that major world trading markets believe that they equally cannot get behind in the race to exploit the technology.

(b) *Independence of Advisers*

Many of the scientists and academics that would historically be relied on to provide independent advice on behalf of the community now have strong dependencies on industry. As a result we believe that many of the advisory bodies at EU and UK level have a strong bias towards bringing this technology to market. When deliberating issues it is within the context that the approval of these products must not be delayed rather than proceeding with due caution.

(c) *Compartmentalisation of the Review Procedure*

As with this Sub-Committee particular aspects of the approval process tend to be dealt with separately. However in order to decide whether or not these products should come to market the benefits must be balanced by consideration of all the accumulative impacts. Hence the fact that a product may pass an environmental assessment in isolation should not remove the need for the environmental impact that does exist to be considered in the final equation.

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(d) *Products On The Market Before The Controls*

Perhaps with this background we should not be surprised that at both EU and UK level the authorities have failed the consumer. We should all be embarrassed that we have the new GM commodity crops on the market before we have appropriate controls in place to allay the fears of the consumer.

We believe that the biotech industry only has itself to blame for the delays in their new products being approved. They could have been proactive in determining the appropriate practical controls with consumers' interests in mind rather than lobbying for the authorities to consider the possible impact of trading relationships and denying the concerns of the consumer.

(a) *Consumer Link with BSE*

We have been amazed that it has taken so long to recognise that the European consumer might be a little concerned about scientists playing with their food so soon after the BSE scare. The two issues may have no connection technically but that is not the view of the consumer. When GM soya was introduced we felt that the industry had something to hide because of their negative attitude to the wishes of the UK retail trade.

As with the BSE situation food operators must be able to rely on the advice provided by the competent authority. After the BSE scare we are now understandably not as confident in these authorities.

2. 90/220/EEC—RELEASE INTO THE ENVIRONMENT

(a) *Agreed Timescales for Reviews*

The provision of agreed periods for reviews to be completed should make the process more efficient. The timescales act as a good guide but in practice we feel that some of the timescales may be difficult to comply with. Whether the system works in practice will depend on the pressure on the committee to approve the product or to throw the application back when there are grey areas, and further expert advice is required to make the decision. At present this may not be an issue but if the number of applications increases as expected difficulties may arise.

(b) *Transparency and Consumer Involvement*

The proposed greater transparency of the decision making process and the involvement of consumer groups is welcomed. Effective debate with consumer groups across Europe may be difficult to facilitate in the timescales suggested (30 days).

(c) *Segregation—Cross Pollination—Cross Contamination*

Iceland has achieved segregation of GM Ingredients and no Iceland Own Label products are currently made with GM Ingredients.

If we are going to be able to maintain the segregation of a non-GM alternative we must limit the risks from cross pollination. We understand that in the US some states have introduced controls that prevent the growing of crops which may increase the likelihood of pesticides resistance being gained. In the UK we are concerned that if GM oilseed rape is planted this will quickly contaminate Non-GM crops. We understand that oilseed rape cross pollination can occur over a substantial range. At present trial plots are planted at least 50 metres from the nearest farmer with a six metres gap round the outside of the crop. This may not be sufficient. Once crops are approved similar controls must be implemented if Non-GM crops are not to be contaminated. Regional segregation for oilseed rape should be mandatory if practical farm segregation distances cannot be found. In addition haulage controls for seed would need to be introduced to prevent the current spread of seed along haulage routes.

We believe that farmers that wish to maintain a Non-GM crop should have an ability to claim compensation if their crop is contaminated by a neighbour's GM crop or they incur greater costs due to having to use herbicides to remove GM weeds.

(d) *Fixed Approval Period*

Once products are released into the environment the DNA structure continues to evolve. Materials that were deemed to present no risk to consumers or the environment may create problems due to the presence of foreign DNA. The environmental impact of GM crops may also take some time before it becomes evident. We thus

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support the proposal for approvals to be given for a limited period. We believe that the criteria for a continuation need to be well defined to ensure a thorough but practical review is completed of all key areas. We would like to see more details as to what exactly is required to pass such a review.

(e) *Monitoring*

The key criteria for monitoring the implementation of GM crops should be specified as part of the amendment or within an agreed period. At present this is to be decided on a case by case basis when appropriate. This is too vague. Food safety and environmental impact assessments should be completed. Even so monitoring is difficult unless segregation is maintained.

(f) *Substantial Equivalence—Gene Stacking*

We are still concerned at the use of “substantial equivalence” and believe that the failure to require a full DNA profile will allow foreign proteins to be missed. Allergy testing must be completed on humans and be based on the product as intended to be placed on the market rather than, for example, the DNA to be inserted or the intended GM protein.

With gene stacking providing several traits in one crop we believe approval should again be sought. At present it is expected that once a genetic modification is approved additional changes still maintain the substantial equivalence criteria.

(g) *Terminator Genes*

We are also concerned about the approval of “terminator” traits which prevent the farmer from retaining seed for the following year. We understand the need to protect intellectual property rights but believe that this trait may be used to exploit farmers.

3. (EC)258/97—NOVEL FOODS/INGREDIENTS

(a) *Labelling*

We support the changes that have been made to the Novel Foods regulations on 26 May. The labelling changes are more practical for those that wish to sell GM products.

As ever the period for implementation is inadequate even at 90 days, when considering the number of products affected. For long life products such as grocery and frozen products it is not unusual to print packaging once per year. We assume that as usual enforcement officers will be asked to take a pragmatic approach.

We are still concerned that some ingredients derived from GM crops will not be identified to consumers, such as oil. We believe that consumer pressure will continue to build and this will be amended eventually. We have already removed all GM soya derivatives from our Own Label range whether or not the DNA is present.

We are concerned that lecithin may either be treated as an additive, or if the appropriate purity criteria are not met, lecithin would be placed on the ingredient exemption list for labelling. Lecithin clearly contains GM DNA.

(b) *Threshold Values*

The introduction of a threshold for Non-GM products is essential if customers are to be given a Non-GM alternative. Having established ID preserved materials we are building a picture of the ability of our suppliers to minimise co-mingling.

4. THE FUTURE

It is pleasing to see that some of the biotech companies are now acknowledging that consumers should be given the choice of Non-GM alternatives and that segregation is possible. We are looking forward to working with anyone who genuinely has these aims. We are confident that we will be able to re-establish trade with our traditional sources as well as supporting those that have helped Iceland make this a possibility.

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[Continued

Examination of Witness

MR RICHARD WADSWORTH, Technical Manager, Iceland Group plc, called in and examined.

Chairman

160. Good morning, Mr Wadsworth. May I welcome you to the Sub-Committee. Thank you very much for coming to assist us in our enquiry into genetic modification in agriculture with particular reference to the European Community regulation. You have kindly sent us a paper which is very useful. You gave a brief introduction to Iceland. I wonder if I could start by asking you to expand slightly on that? You mention the size of Iceland Frozen Foods. Could you perhaps put that in the context of the industry as a whole, in terms of your market share both as far as frozen food goes and retail generally?

(Mr Wadsworth) It is about three per cent of the grocery market and about 17 per cent of the frozen market.

Lord Wade of Chorlton

161. I think the Committee would be interested to know just how you adopted this anti-GM approach and whether it is entirely because of visions of principle within the company or whether it was decided on the commercial benefits that might come from it. Following on from that, we would be interested to know, as a result of your answer to that question, if in fact it has proved commercially justifiable and what the commercial impact has been upon the business. Perhaps I could add to that that, if it was a matter of principle, then what sort of changes would you wish to see that would make genetically modified foods acceptable?

A. The board of Iceland are concerned about the technology and possible dangers to health, the environment and the fact that the approval controls for GM foods are inadequate and rudimentary by comparison to GM approvals in the pharmaceutical area. If you consider for example the benefits that might come to society from work on GM products in the medical area, the controls in that area are much stricter. The benefits in the agricultural sector are much less and yet the controls are less. The balance does not seem to be correct. They also believe that customers are being denied the choice by the failure to segregate the commodity crops. From a corporate view, and this is the main reason for making the Iceland brand GM-free, our research shows that the majority of customers, over 80 per cent, want a choice, so this has to be a good commercial decision. With regard to the actual justification commercially, since January of this year we have seen like for like sales gains of 14 per cent. It would thus appear that the approach has been commercially justified, although some of this improvement in our sales performance will be down to other activities, such as the introduction of home delivery and the special deals that we have on offer.

Chairman

162. So your objection is not really on principle? You are not calling for a ban on all genetically modified foods? I suppose you could not really because your *raison d'être* as a company in supplying modern genetically unmodified foods would not any longer exist.

A. The key issue here is about the fact that genetic modification can provide significant benefits for society but we have to balance it with the risks that are present. What we are saying is that the debate that has been going on has not been raised with the consumer's interests at heart and that is what we are trying to do. We are trying to raise the profile of the debate and get consumers involved, make sure the authorities have the appropriate controls for the introduction of these products and give the consumers the choice. If the consumers then choose to buy biotechnology products, that is then their choice but they have to be informed about what is going on and they have to be protected by the approval system to make sure that the products are acceptable.

Lord Gallacher

163. Mr Wadsworth, how widely across the product range have you extended your non-genetic modification policy?

A. We currently have approximately 2,000 lines, just over 1,000 of which are Iceland brand. Of these approximately 400 were affected by the introduction of the commodity crop such as soya. All of our brand range is now being made with non-GM beans.

164. In view of that extension are you finding any problems with supply?

A. In trying to establish supply in the first place that was difficult. We had to completely change the way that we buy in foods. Normally we would approach manufacturers and they would approach their manufacturers and the raw materials suppliers for the GM-free materials that we are looking for. When we tried to do this we approached our supply base. They said it was too difficult to do, so we approached organisations like IGD and the FDF to see if they would be able to help through the trade associations. What it came down to at the end of the day was the fact that if a manufacturer is trying to buy a small quantity of non-GM material it is not viable. The costs of segregating that small quantity of material are too great and that is what everybody was saying. They were all saying it was impossible. What we have had to do is completely re-think the process. We have approached all of our supply base and we have obtained the quantities and materials specifications that they require for the raw materials. We then amalgamated that information and went out to seek non-GM soya beans at source and then bring the bulk quantity that we now require back through the supply chain. We have had to go completely to new sources

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[Continued]

[Lord Gallacher Contd]

of supply and we as a retailer are now buying in bulk non-GM materials and supplying those not just to our own suppliers but to anybody else who wishes to buy them. In terms of maintaining that supply, yes, it will become more difficult as more products come on to the market that are GM. We are already working on trying to make sure that the maize that was planted in France this year will be segregated and, if not, that we will have appropriate plans in place to make sure that we can obtain materials that we wish to obtain.

Lord Redesdale

165. The work you have undertaken must have had quite a large cost implication. How do you justify that?

A. You talk about a large cost implication. In fact the costs are greatly exaggerated in terms of trying to get these schemes established. The reality was that once we actually raised the awareness to the industry that we were very concerned about the introduction of genetically modified crops and that we did want to provide a choice and that we were going to do everything we could, we then had quite a few companies that made contact with us offering supply and offering help. We have had a great deal of help in trying to identify sources of materials. For example, Brazil had no non-GM soya planted at the time that we were all seeking it and they had vast quantities of material and yet nobody had actually really been able to get in contact with the right people in that country. Once we made people aware that we wanted that sort of material it was actually our friends and colleagues in America that helped us find the material in Brazil that we were looking for. That helped us reduce the cost of seeking the materials. Yes, there have been costs of people going over to Brazil to look at plants and check the plants out. There has been a cost in terms of verifying the plant and making sure that that plant can produce non-GM product consistently to the quality that we require, but in the scheme of things the actual costs are not as great as you might imagine.

Baroness Young of Old Scone

166. Consumers are worried about other sorts of technologies for the production of food as well, for example irradiation. Do you have a similar policy for other technologies in the production of food?

A. Our involvement with this issue does not actually signal a change in the position of Iceland. This is a particular issue that we actually felt very strongly about. However, we do have a policy which prohibits suppliers of our own brand products from using irradiation. We also will be opposing the use of growth hormones to increase milk production as this is in our view clearly unnecessary. It is not new for Iceland to be raising issues on behalf of consumers. However, often this work goes on unnoticed as it is done through trade associations, and when people work together to resolve issues then that does not get into the media. It is when we try to resolve those issues and are unable to through the normal channels that it becomes more of a debate in the open.

167. I was interested in your evidence that you seemed to indicate that you were doing this because consumer concern was there but that it was quite difficult to get corresponding independent scientific advice because of a bias in the scientific voice, and that was quite surprising. Perhaps you could enlarge on that.

A. It is our view that historically people would go to academics for an independent view which would actually provide advice on behalf of the community, and often governments have relied on that source of expertise to provide an independent view. The difficulty now is that so many of the academics are involved in biotechnology and that is where you are getting your expertise from. Governments are interested in this area and are spending millions of pounds investing in academic research because of the race to exploit this technology. There was a recent article suggesting that there will be three million people employed in biotechnology by the year 2005. Governments and trade areas do not wish to be left behind on that development of business. Our view is that certainly, as we have seen in the development of regulations, there is a strong bias to try to help get these products to market. The fact that we have had to change the regulations several times, including labelling, clearly shows that those experts were not considering the consumers' views initially. Those consumer views are not new. Those views were known two years ago and yet the expert advice that has gone to Government has not provided protection to the consumers. When we seek clarification from the Committees we tried to work through the trade associations to get answers to some of our questions. Initially it was very difficult. In fact we have had a response through the British Retail Consortium which suggested that it was not the duty of the Chairman of the Advisory Committee for Novel Foods to respond to trade associations about their enquiries. They also suggested that they could not consider any item which was slightly outside the scope of their investigation. Clearly that has been wrong and this debate has been going on between the trade associations and the advisory committees for some time. When you then see members of the advisory committees openly defending the biotech industry on TV programmes, then it does worry us that perhaps the independence of these committees is not as balanced as it should be. We are not suggesting that these academics are deliberately trying to let products through, but it is very difficult to be truly independent. We would like to see on these committees a little bit more of a balance of people that have consumer interests at heart, whether it be consumer associations or, to be honest, in our view, members of the trade, whether that be retailers or manufacturers, and even those that may support biotechnology. We believe this would give a better balance in those advisory committees to the work that is going on in them. We had a situation last week where one of the members of the Advisory Committee suggested that there had not been any accidents. Now, it is difficult for us to find out the details, but we were informed by somebody from the biotechnology group that in actual fact some oil-seed

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[Baroness Young of Old Scone *Contd*]

rape had been planted in the United Kingdom accidentally outside the trial plots and had to be ploughed in. Now, if that is not an accident, then I do not know what is and if the person involved who is actually on the Advisory Committee does not know about that, then they should, so I am concerned about that. It is very difficult for us actually to suggest any particular queries other than general issues, but we would like to see a far better balance and certainly the actual track record is the proof that consumer interests have not been at the heart of some of the decisions.

Lord Gisborough

168. On what sort of scale has your approach been copied by other retailers?

A. We understand that Sainsbury's and Tesco's both now use non-GM material. They are actually trying to remove the soya protein elements in their own-brand products, but they are not removing the non-protein derivatives, such as soya oil. Recently the level of products converted to non-GM quoted was actually 90 per cent for Sainsbury's and 70 per cent for Tesco's. One of the main difficulties for anyone trying to move on to the non-GM is actually trying to find the sources, as we indicated earlier, and that is why at Iceland we have actually established a separate company within the Iceland Group which now provides non-GM materials to anybody who wishes to buy them. We have actually contacted the other retailers and actually offered to make the details available. We have offered assistance and we are in correspondence with one or two of them, so we do expect to see more people following Iceland in the United Kingdom. I would like just to add to that that we have also been contacted by retailing groups across Europe and have recently been over to the German equivalent of the British Retail Consortium actually sharing our experience with them, so we do expect other retailers across Europe also to follow.

Lord Rathcavan

169. We have seen an enormous explosion in the growth of some GM crops in North America, particularly soya and maize. Do you think that your approach of segregation is sustainable in the long term and is segregation by producers similarly sustainable?

A. Ultimately, this will be decided by the consumer. If they continue to confirm their wish to buy non-GM products by changing their shopping habits, we believe that the demand will grow, and as it does, it will improve the chances of us maintaining our stance. A key issue in the United Kingdom will be the controls in place for the planting of new crops and particularly with oil-seed rape. Cross-pollination of this crop can occur over considerable distances. If farmers are allowed to contaminate non-GM crops with genes from GM plants from cross-pollination, then this will make our life very difficult. More immediate is the problem in France where GM maize has been grown this year and the industry is still determined to mix this with conventional stock. We really are looking to make sure that this is actually

segregated and if the industry is not prepared to segregate that material, we will be pushing for some kind of regulation to make sure that it is, particularly while the debate is still going on. So in terms of long-term sustainability, as new crops come on stream, it does become more difficult. However, as the demand grows, then more sources are open to us, so it is difficult for me to predict. I was going then to go on to the second part of the question which is actually regarding producers and the segregation of materials within their sites, the manufacturing sites. This actually is not necessarily particularly difficult if you think that they handle many critical products and raw materials and they have to provide segregation and traceability for those materials, and that is part of providing good-quality and safe foods. We do not see that the GM issue will actually create any more difficulties for the manufacturers in actually providing the supply that we require and the traceability that we require; the techniques are ones they have used. It is an added problem, but in actual fact the actual techniques used are the same as for controlling other raw materials.

Chairman

170. Is it very demanding on your manpower to ensure the traceability and segregation of overseas products which are produced for you?

A. In terms of manpower, not particularly again because it is not as if at this time we are using hundreds of sources. We have a particular source in Canada and a particular source in Brazil, so that is two primary sites that we need to watch over and the controls then in Canada are being operated to farm level by the operation in Canada and paid for by the operation in Canada, so in terms of our resource, then that is limited. What comes down to the work that we have had to do is actually going through all the ingredients in our products with our supply base and identifying all of those which might contain GM material, like soya and maize. That takes some time.

Lord Rathcavan

171. Taking into account the extra management effort you have had to put in and the extra overhead that you have created, what is the percentage extra cost of your soya compared to the commodity soya? Are you able to put a figure on that? At the moment obviously you are operating on a fairly small base.

A. In terms of the actual soya material that we are purchasing, we can confirm that the soya flour we are buying we are actually buying at the same price as the soya flour that we were buying before. There is no added cost to a manufacturer for buying non-GM soya flour. We are also able to buy soya protein isolates and soya protein concentrates, on balance, at the same price, one slightly higher and one slightly less. The only product material that is actually costing us more is soya lecithin. Soya lecithin is actually used in the manufacture of chocolate as an emulsifier and that material from Brazil is costing approximately 10 to 15 per cent more than the GM material. We are working

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[Continued]

[Lord Rathcavan *Contd*]

with the Brazilians to reduce that cost and we are hopeful that we will be able to bring that back down to the normal price. The reason for this similar price comparison is that at the moment the difficulties of segregation are less because the areas where we are buying materials from actually do not plant a great deal of GM material. When the level of GM presence in the whole market grows, then the difficulties of identifying and preventing cross-contamination will grow. For example, in Brazil, Brazil was not growing GM crops and, therefore, you had a good deal of certainty about the actual material that you were buying. As time goes on and they start to plant GM crops, then watching for materials being co-mingled and cross-pollination will be more difficult and may incur more costs. At this time the actual cost increase is minimal but in the future that might increase.

Chairman

172. You refer to difficulties in segregating oil-seed rape. In your paper you refer to the possibility of drastic solutions being requested by you, namely regional segregation. Could you say a bit more about what you have in mind when you talk about regional segregation of oil-seed rape?

A. Well, simply that I understand that when biotech companies want to keep their GM crops separate because of the chance of resistance going from one crop to another, as in certain states in America, I understand that they have a simple rule that you will only grow one crop and not the other crop. It is quite possible to conceive of the fact that you may turn around and say, "In this county you can grow a GM crop and in that county you cannot". That would allow for very clear segregation of materials. It of course should be based on not just a regional area as a county necessarily, but also the collection points for the materials, so you keep one collection point and channel clean for non-GM and another collection point and channel, and the associated farms, can then handle GM material. That would be a way of actually maintaining segregation. It is either that or you have to have spacial separation between a farm that wishes to keep their crop non-GM and any other farm around that wants to plant GM, and that I can imagine would be quite difficult.

Lord Wade of Chorlton

173. Who would have the authority to tell a farmer what he should grow, not grow and where?

A. That would be the Ministry.

174. But nobody is suggesting that that is going to happen.

A. That was one suggestion.

175. From whom?

A. From ourselves in terms of a possibility that you can make regulations about what is grown and provide a provisional licence, if you like.

176. But nobody has accepted that responsibility to authorise what people should grow and what they should not grow; it is free will.

A. What I am saying is that apart from some of the biotech companies which have very strict contracts with farmers about what they will grow and what they will not grow.

177. But that is a freely-entered-into contract.

A. I accept that and what we are really saying is that we have to find a way of providing farmers who wish to continue to provide non-GM crops with an ability to do so.

178. What I do not understand is why have they not got that ability to do so? If somebody wants to grow a non-GM crop, who is to stop him?

A. Because the farmer next door may actually produce a GM crop and with cross-pollination, within two or three years his crop will be contaminated and he will not be able to sell his crop as a non-GM crop and that seems to me to be wrong.

Lord Willoughby de Broke

179. Mr Wadsworth, you have already touched on the question I wanted to ask you in your earlier answers when you described the way you sourced your soya from Brazil and Canada. The American producers say that it is almost impossible to segregate the soya, but if there was a significant enough market in the EU, could there be a rethink on behalf of those producers, do you think?

A. Well, in addition to our current sources which are outside the US, we are already working to provide non-GM soya derivatives from America. We are on target to achieve the supply of identity-preserved US soya derivatives from the 1998 crop. As a result of our activity, we have persuaded the American Soybean Association to moderate its stance in this area. Although they do still believe that the mass segregation of non-GM soya from GM soya is not achievable, they are now identifying suppliers' details for those that are able to provide an identity-preserved material which, in our view, is equivalent to segregation. This is a significant change and will open up many more opportunities for us to work back through our traditional supplies. It has never been our intention to try to move away from the current supplies from America because we have no problems with American supplies, but all we wanted was an availability of their non-GM material.

Lord Grantchester

180. You have raised the subject of segregation for growing crops, but, generally speaking at the moment, do you see a role for government in requiring segregation of crops already in the market, or do you see this as pressure of to be exerted through commercial contracts?

A. The simple answer to that is yes. We have long argued for the matter to be left to the market. However, the refusal of the biotech industry to work with the rest of the trade on this matter means in this case that we do seem to appear to need regulatory controls, and most of the reasons for that have been indicated in the submission I have provided.

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[Continued

Chairman

181. You refer to a refusal of the biotechnology industry to work with the retail trade. Could you amplify a bit that refusal of the biotechnology industry to work with the retail trade?

A. Well, if we go back a little while, the British Retail Consortium actually was aware of the consumer concerns regarding biotechnology and has been for some time. You have to remember that in the United Kingdom we are all aware of the BSE issue and the fact that consumers were bound to be concerned about hearing that scientists were again playing with their food in what appears to be an unnatural way. Therefore, the British Retail Consortium actually had a policy which sought segregation of the GM crops. There was significant dialogue with the American Soybean Association and with Monsanto directly to make sure that when they bought the new biotechnology products to market, they would be segregated and the intention was to make sure that consumers were given a choice, would gain confidence in the new biotechnology products and then there would not be a need for segregation in the long term. That was the intention. The responses that came back from the biotech industry were very positive for almost a year and then after the crop had been planted and put into the chain, we got the answer, "Sorry, it is now mixed and there is nothing we can do". That was not a particularly good way to work with the United Kingdom retail trade. In addition to that, whenever we have actually aired the views of the retailers and the consumers, the stance that has come back is very strongly put that there is no need and it was said once that it was "just backward Europeans who did not like change". I am afraid that that is not a particularly positive attitude to take with a United Kingdom retailer when all we have been trying to do is provide our customers with what they require.

Lord Grantchester

182. Perhaps I could follow up your answer by perhaps suggesting that there might be a role for the Government in segregation, but how do you think that this could go forward and what would be the costs involved? Do you think that this would require supply chains to be dedicated one way or the other? What about traces from one batch of supply to another? How do you see this going forward as a requirement of separation?

A. We already have identified ways in which you can actually keep these crops segregated from our point of view, which is why we have provided a non-GM alternative. Perhaps if I can just go into some of those controls, we might be able to establish how that then would be maintained, if that would be appropriate. We basically control our non-GM products with a combination of testing and audit trail, as we would do actually with any other critical material. In Canada, the organic food model has been used, so we use certified seed and then at each stage of the process we actually have people who audit the sites to make sure that the material is being segregated and actually provide a certificate the next day to say

that that material came from a non-GM crop. Then in order to remove the issue regarding segregation during shipping, we have been shipping a whole shipment of non-GM material. That material then goes to a site that only deals with non-GM material, so in the case of the Canadian supply, it is going to a flour mill, which is Spillar's, and that site is totally Non-GM. As we do not need a great deal of that material, so any excess material we then put back into the normal commodity market at normal commodity prices. Nobody is particularly bothered if we actually co-mingle non-GM into a GM crop, so, therefore, that is what we are doing. By doing so, you have an excess of material that you do not require. This why we can openly make it available to other people and, if you would like, we have more details on the specific controls from Spillar's Premier Products and we could leave you a copy of that to look through. In Brazil, the situation is slightly different. In that case, the actual site that we are using has control over the farms that it buys the actual beans from in that it operates through a co-operative system, so they provide the seed to the co-operative farmers and the farmers then supply the beans back. They are already doing some field-work in order to establish that those farmers are truly growing a non-GM crop before the beans are produced. They can test the leaves for the DNA presence and make sure that it is clear. As the site that is receiving the beans processes the materials all the way through to the finished raw material, in this case soya lecithin or soya protein isolates, then there is no problem with co-mingling on that site. Then when we are sending the finished product, (the raw material for our suppliers), we are sending it in drums and in bags and, therefore, in the shipment there is no problem with co-mingling, so a great deal of the issues regarding the segregation can be resolved in that way. The site in Brazil has doubled the size of its capacity in the last year and has plans to double again next year, so in terms of volume capacity, it is perfectly feasible, and obviously we have paid a great deal of attention to soya and that is because it is a first commodity crop, but once we have that established, then we think that as new GM crops come on, people will see opportunities for them to have a niche market and we see that being perfectly possible.

Lord Moran

183. You did include a piece about labelling in your memorandum of 4th June and I wondered whether you were happy with the Council agreement which they made recently on labelling and whether you think that labelling should go further than simply saying that a product is genetically modified and perhaps say why it has been modified, as is the case, I think, in Canada?

A. We have to say that the recent amendment to the labelling proposals we generally support and it is a very positive move. It is much clearer to those who wish to provide GM products as to how to do that and the message to the consumer will be much clearer, so we generally support the changes which have recently been made. Our key concern is that all ingredients derived from a GM crop will not actually be labelled.

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[Continued]

[Lord Moran *Contd*]

The soya oil will not necessarily be required to be labelled. The difficulty here is that if you have an issue with genetic modification because of the ethics of it, then certainly you would want to know that that soya oil is present. If it is the fact that, as a consumer, you are concerned about the fact that you do not wish to eat the DNA material, then the issue here is that there are other products, such as lecithin. This does actually contain the DNA material, but because lecithin is considered to be an additive, it is not included in the labelling requirements. People will still be eating GM DNA and it will not be labelled, so the labelling does not quite go far enough in terms of its requirement, so we are concerned about this.

184. Can those problems be overcome, do you think? Is there a practical way in which it can be done?

A. Well, certainly at EU level they need to consider additives, eg. colours and flavours. It is not unusual to have soya oil, for example, used to disperse colours and quite often materials like hydrolysed vegetable protein will be found in flavours. It is just simply a question of saying that if we are wishing to label materials which contain GM material, GM DNA, then that should cover all ingredients and this can be accomplished by changes to the regulations. I think that the EU will need to look at the additives and then cover the GM issue in that review.

Chairman

185. What is your view about stating on the label that the GM process has been used even though there is no DNA present in the product?

A. Well, the way we have approached the labelling issue and the removal of GM ingredients is we have already removed, as I have said, the GM ingredients which contain protein and soya isolates and we have also removed the soya oil that does not contain protein. The next level that we are looking at currently is the processing aids and seeing whether in actual fact we should and how we can remove these. Where we can remove them, we are doing so and if we are unable to do so, we will then consider how best to provide information to the consumer. It may be that there are various ways we could do that. If you take chymosin, which is a product of biotechnology used in cheese production, then it may be that the suggestion that vegetarian cheese indicates the presence of chymosin is enough to tell consumers what is in that material, but it may be that that is not enough. We are still working and trying to establish what are all the ramifications of trying to label processing aids and, therefore, determining whether it would be best on the pack or whether it would be best on information provided to the consumers at the point of sale. I think it would depend on the type of modification that is present. We would want to get consumers involved and ask them what do they want to know about and where do they want that information and what they believe to be practical for the trade.

186. Can I ask your views about the EC regulatory system? Do you have any major problems with it as a retailer and are you aware of any that others in the

retailing industry in this country have of the EC regulatory system? What are your comments on it and its operation?

A. I suppose in this case the main problem is that the regulations were not particularly well thought out originally and were quite badly drafted with almost impossible periods of compliance. We can almost guarantee that under European law these days there will be an amendment to it when somebody sees sense. What we have to do is guess what those changes will be and what will be the outcome of them and then go down that path and try and make sure that we can comply. An example of that is with thresholds. We have gone down the line of providing a non-GM alternative and we have to have thresholds to be able to do this. We had to go down the route of supplying the non-GM alternative before we got the regulations changed which might have meant that we would have ended up in court having to defend the fact that we were giving consumers a choice. We were prepared to do that because we believed in what we were doing. That is clearly a nonsense. With the labelling changes which have just come through, they did extend the dates for compliance, but for those that are selling GM products, they have 90 days to change the labels, which, if you can imagine for frozen products and grocery products with a long shelf-life, you may only revamp the packaging or make the packaging once a year, so there is no way you can easily and readily change thousands of labels in 90 days. Unfortunately the regulators still do not seem to understand the difficulties of complying in time. When we do get amendments to regulations for consideration, as a larger retailer in a trade association we are very fortunate in the United Kingdom that we do get the information through fairly quickly, but the timescales we are talking of for consultation are often in terms of days, not weeks, and it is very difficult to get a consensus view, a proper decision and a proper debate in that time-frame, so we still have difficulties in that area. Some of the specifics that we are trying to handle at the moment include quantitative ingredient declarations where we have had to put the percentage of the key ingredients on the packs for consumers. Now, we were hoping to have most of the products actually labelled with quantitative ingredient declarations by the summer and yet we are still waiting for a definition from the EU as to what meat is because each country in the EU has a different definition as to what part of an animal can be used. Now, until we get that definition, we cannot actually comply and yet we are being pushed to comply now, so you can see the sort of debate there that is going on. We have the XAP system for beef exports which actually now requires substantial veterinary supervision of plants. We understand why, but simply what that has done is it has actually made the export of beef products, using foreign beef, unviable and this loses to us the continuity of contacts needed for when we can sell British beef. We have had the situation with the licensing of butchers which was introduced for good reasons after the E-coli food scares, but initially it was going to cover all food retailers who handled fresh meat and it did not consider originally the fact that

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MR RICHARD WADSWORTH

[Continued

[Chairman *Contd*]

many people actually handled meat already packaged. Here there is no risk of cross-contamination, so we have had again to lobby very quickly to get that regulation changed actually to make sense. Those are just a few examples of the sort of things where unfortunately, as a retailer, you cannot just sit back and let things happen and hope the regulations come out right. You have to take a proactive role and unless you have the resources to do that, you cannot get involved, so the smaller retailers and the smaller manufacturers get left behind and unfortunately they do suffer greatly through EU regulations. So it is important to get everybody involved early enough to get the discussions going and make sure that the decisions that come out within the regulations have been thought through in practice.

187. What about the wider international level? Is there going to be a growing problem of importing products from third countries and not having the slightest idea as to whether they contain GM ingredients or not?

A. Absolutely. This is the whole problem with biotechnology and the way it is going. Everyone has talked about soya greatly and soya, to be fair to the biotech industry and Monsanto, has been looked at under the microscope, so you can be sure that soya in its present state will be safe. The difficulty is going to be that very quickly you are going to have thousands

of complications of changes to plants and animals in Europe and in America, never mind in Third World countries. Unless the regulatory system can guarantee that any imports are controlled, then, as a retailer, there is no way that we will be able to keep up. This is why we are saying that we have to rely on the advisory committees and we have to rely on the Government and they have to be the people who control the monitoring, surveillance, like they do with pesticides, to make sure that these products are safe and sound for us to be able to use. We, as retailers, should not have to be going into doing research into supply chains; it is a nonsense. We should be selling food from manufacturers knowing that it is already safe, acceptable and correctly labelled and that should be the same for them buying from the agricultural sector or when they import products. This is one of the reasons why biotechnology, we do believe, will provide benefits and it is coming, but it has to be controlled and everybody has to know now the significance of what is going to happen in the future. It is very, very difficult.

Chairman] Thank you very much. I think that brings us to the end of the questions we have and we are very grateful to you, Mr Wadsworth, for having come and helped us on this enquiry by putting the unique point of view of your company within the retail trade on this subject, which is extremely valuable. Thank you very much indeed.

WEDNESDAY 17 JUNE 1998

Present:

Gallacher, L.	Reay, L. (Chairman)
Gisborough, L.	Redesdale, L.
Grantchester, L.	Wade of Chorlton, L.
Jopling, L.	Willoughby de Broke, L.
Moran, L.	
Rathcavan, L.	Clanwilliam, E

Memorandum by the Green Alliance

INTRODUCTION

1. The Green Alliance (GA) is one of the UK's leading environmental policy organisations. The Green Alliance biotechnology programme has been active since 1987, and the GA has played an important role in raising awareness about the potential environmental consequences of releasing GMOs, as well as campaigning for greater transparency of the regulatory system. Julie Hill, former Director of The Green Alliance and now Programme Advisor to the organisation, has since 1990 been a member of the UK Government's Advisory Committee on Releases into the Environment (ACRE). The GA thus has considerable experience of the development and operation of the EU regulatory system, its implementation in UK law and associated policy, and the concerns of non-governmental organisations.

1. *The appropriateness and efficacy of current regulation of release into the environment at European Level*
 — *The scope of 90/220 must be clarified to ensure that indirect effects are considered*

2. Directive 90/220 requires that "Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs".

3. One of the problems in implementing the Directive has been that "adverse effects" are not defined—it is left up to member states to decide what constitutes an adverse effect. This has led to considerable differences in interpretation among member states, culminating in fierce disagreement as to whether particular products should be allowed to enter the market. One of the main disagreements has been over how far "indirect" environmental effects should be taken into account—the most prominent of these being the effects of the use of a chemical in conjunction with a GMO, as happens with herbicide tolerant crops. The UK has been one of the Member States arguing for a relatively narrow interpretation of the Directive, one that excludes indirect effects.

4. It is in everyone's interest to clarify the scope of the Directive—the delays caused by these disputes have been time-consuming and costly, not least for the applicants. In the most recent draft of the proposed revision of the Directive, "indirect" as well as "direct risks" are included in the definition of what environmental risk assessment should cover, but there is no guidance as to how this should be interpreted. It should be made clear that the Directive regulates "indirect" as well as "direct" effects and these should be defined, so far as is possible.

5. By recognising the importance of indirect effects, the Directive will be moving towards ensuring a fuller environmental "audit" of the applications of the technology in agriculture. Biotechnology companies are presenting their products as more "environmentally friendly" and arguing that they will lead to a decrease in the use of damaging pesticides, but as yet they have provided very little independent evidence that this is the case. The public is looking to the regulatory authorities to provide a judgment on these issues—so far they have abrogated this responsibility.

— *There should be guidance in the Directive as to what constitutes an unacceptable risk from GMOs*

6. The revised Directive attempts to set up principles for risk assessment (Annex II). This gives guidance on the kind of questions that should be asked in order to assess the risks posed by a GMO, but gives no guidance on how the answers should be judged. As noted above, in the absence of any definition of "adverse effects", member states are left to come to their own views as to what constitutes an unacceptable effect from a GMO, and have already tended to disagree.

7. The Directive should provide guidance on the acceptability of impacts. In order to do so, the Commission and Member States will have to engage in a very broad debate about the value we place on the natural environment, and what should be considered an unacceptable burden on it. It should also be debated whether GMOs should be judged by reference to other agricultural practices, for instance the spraying of chemical controls, or whether there should be an independent standard for damage by GMOs.

— *The Directive should require that risk assessments explicitly acknowledge areas of uncertainty before coming to a general conclusion about risk.*

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8. One of the problems for risk assessment in this area is the large degree of uncertainty about long-term effects of releases. The Principles for Risk Assessment in Annex II of the draft revised Directive give no guidance as to how to handle uncertainty, and uncertainties are rarely acknowledged by the Member States when they give their verdicts on an application for a consent. The effect of this, particularly for marketing consents, has been a severe lack of confidence in the way political systems are using science, and diminishing credibility of scientific experts. Acknowledging uncertainty is an important step towards remedying this.

— *The Directive should require Member States to consider the cumulative impacts of GMO releases*

9. The Directive provides for risk assessment and consent procedures for individual applications for release or marketing. Although not specifically prohibited by the Directive, this framework tends to limit the ability of Member States to consider the cumulative impacts of a variety of GMOs, released at increasing scale, over time. Herbicide tolerant oil-seed rape has provided a potent illustration of this problem—individual applications for a single type of tolerance, used on a small scale at trial stage are judged not to be a problem. However, there is an increasing feeling that the cumulative effects when the crops reach commercial stage could be very serious—they include the possibility of volunteers with multiple tolerance and dramatic changes to patterns of chemical use. The same problem is posed by different types of insect-resistant crops.

10. A more strategic view, considering cumulative effects, would provide important context for individual consents, which otherwise tend to be seen in isolation from each other. The Directive should require that Member States periodically review the releases already in progress in their country, and identify any cumulative impacts that should be addressed—by, for instance, discontinuing consents for certain types of release.

— *There must be post-commercialisation monitoring of GMO products*

11. In the recent draft revision of the Directive, those applying for a consent to market a GMO product must submit plans for monitoring “to identify any relevant direct, indirect, immediate or delayed effects of the GMOs on human health and/or the environment” (Article 15.2). This is linked to a proposal that consents are limited to seven years. We welcome these proposals, although we are firmly of the view that monitoring should not be seen as a substitute for thorough risk assessment when the application is first processed.

12. We acknowledge that finding scientifically credible and practicable methods of monitoring the long-term environmental impact of GMOs will be challenging not impossible. The Green Alliance is planning a pan-European workshop for the end of 1998 which will bring together representatives of non-government groups and scientific experts to debate options for monitoring.

— *The transparency of the Directive should be improved*

13. In the recent draft revision of the Directive, there are new provisions for public consultation. For applications for marketing consents, a summary will be made available to the public by the Commission, and a period of 30 days allowed for comment. Copies of the assessment report, which is the report made by the Member State Competent Authority to which the notification is first made, and copies of opinions from any scientific committees consulted, will only be made available after a decision has been made. There is also provision for releasing some information about experimental releases (Article 26). Article 19 of the original Directive (now Article 28) that requires that commercially sensitive information is not disclosed, remains in place. There is a further public consultation measure in Article 18.3, which requires the Commission to make available to the public any proposals for “simplified procedures” i.e., proposals from Member States to administer the consent system in a more streamlined way. The public will have 60 days to comment on these. This means that the public will be able to express views not just on individual applications but also on procedures.

14. We welcome these developments. However, we consider that the comment time on summary marketing consents is too short—60 days is more realistic. Further, the assessment reports should be made available before a final decision is made, to enable the public to comment on these. There is no case for keeping these secret—it makes a nonsense of any claims to transparency.

— *The relationship between the central scientific committees and those giving advice to the Competent Authorities in Member States must be clarified.*

15. The draft revised Directive provides that “The relevant Scientific Committee(s) shall be consulted by the Commission on any matter . . .” It is assumed that this refers to the committees set up under the auspices of DGXXIV, and which have recently been asked to provide opinions on applications for marketing consents where the Member States have not been able to reach an agreement. This includes the case of the Ciba-Geigy (now Novartis) Maize, with the ampicillin resistance genes, which the UK Government, on the advice of one of its scientific committees, initially voted against being given commercial consent. The Commission sought advice from three of its scientific committees who found no grounds for refusing the consent, and the Commission pressed ahead with a positive recommendation.

16. This raises questions about the role of the Brussels-based scientific committees vis-a-vis the committees in individual member states—are they there only to comment on differences of scientific opinion, or to re-rehearse all the arguments? Do Member States have a right to give opinions on their opinion, or are they the final recourse for advice? How are members appointed to them? Do concerned citizens in the member states have sufficient access to

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the Brussels-based committees—indeed do they mean that the whole focus of risk assessment procedures shifts to Brussels? These questions must be answered if the system is to recover any credibility.

— *There should be clarification of financial liability*

17. It is not clear that there is adequate provision for compensation for damage caused by GMOs in the national legal systems put in place to implement directive 90/220. Civil liability regimes also vary from country to country. Ideally there should be specific provision in the Directive for strict liability for damage caused by GMOs.

2. *The appropriateness and efficacy of current regulation at the level of the United Kingdom and other Member States*

18. These remarks are confined to the UK situation.

19. All the points above are relevant to regulation in the UK, since its structure and operation are conditioned by the Directive and by on-going discussions between Member States about how it should be implemented (through regular Competent Authorities meetings and specific sub-groups such as the Risk Assessment Group). All the problems cited above are mirrored in the UK. The UK Government should make maximum effort to resolve them at the EU level by taking the opportunities presented by re-negotiation of the Directive, but should at the same time look for UK-based solutions.

— *The UK Government must research “indirect” effects of GMOs on UK biological diversity, and must decide on appropriate controls.*

20. As noted above, the UK is one of the Member States taking a relatively narrow interpretation of the Directive, so there has also been a relatively narrow interpretation of the UK’s legislation, and indirect effects are not deemed to be covered. However, The Department of Transport, Environment and the Regions has recently announced the intention to consult on these indirect effects. We have welcomed this initiative, and have been involved in discussions about how it should be framed. Once the results of the consultation have been analysed, which we hope will be by the end of this year at the latest, the Government must move quickly to put in place appropriate controls. If agreement cannot be reached in Europe to regulate indirect effects through the Directive, the UK Government must find unilateral means of control.

— *The UK Government must develop more detailed guidance on what is “harm” under the legislation.*

21. The UK legislation implementing the Directive (Environmental Protection Act 1990 Part VI) has the purpose of “preventing or minimising any damage to the environment which may arise from the escape or release from human control of genetically modified organisms”. “Damage to the environment” is caused by the “presence in the environment of genetically modified organisms . . . which are capable of causing harm to the living organisms supported by the environment” and “harm” means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property”. As with the Directive, these very broad definitions leave open the detailed interpretation of environmental damage.

22. There is some guidance on what would constitute severe, moderate or low levels of harm to natural populations, but this has not been widely debated or agreed. There should be a UK debate on what might be considered unacceptable impacts on the UK environment, covering both the nature and the scale of those impacts.

— *The UK regulatory system must formalise examination of the cumulative effects of GMO releases.*

23. As framed by the Directive, UK regulation proceeds on a “case-by-case” basis—an application is judged according to the environmental risks it poses as it stands, and consideration is not extended to what would happen if the development was used on a larger scale, or over a long period of time. This is the only practical way to grant individual consents, but it limits the ability of ACRE to take a more strategic view of developments, which may provide a helpful context for individual consents. However, ACRE has taken the initiative to examine the possible cumulative effects of certain types of releases—herbicide tolerant crops were the first to be subject to such a discussion, and insect resistant crops are beginning to come under scrutiny. This initiative should be formalised, so that regular discussions are held about the possible cumulative impact of the releases being undertaken, or planned, for the UK at a given time.

— *Judgments made by the Advisory Committee on Releases into the Environment should explicitly acknowledge areas of uncertainty before coming to a general conclusion about risk.*

24. ACRE has a range of tools for communicating with those outside Government about how its advice has been arrived at. These include comments on the public register, newsletters and the Annual Report, news releases, and there will shortly be reports of each meeting. These tools should be used to acknowledge areas of scientific uncertainty in the risk assessment process.

— *There must be post-commercialisation monitoring of GMO products.*

25. UK systems for monitoring the environmental impact of commercial releases should be developed and should not be delayed until agreement on monitoring is reached in Europe.

— *Transparency must be promoted in the UK.*

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26. The transparency of the UK regulatory system, including the accessibility of the Advisory Committee on Releases into the Environment, has improved a great deal. It is now possible to have access to most of the information in the application (bar that agreed by the Secretariat as being commercially sensitive); comments by ACRE following discussion of the application; agendas of ACRE meetings; and there will shortly be reports of ACRE meetings.

27. However, it is clear that still relatively few people know about the role and day-to-day operation of ACRE, and more proactive measures are needed to ensure that concerned organisations and members of the public can transmit their views to the Committee and to the system of which it forms a part. This would be facilitated by public meetings, with widely publicised agendas, in different parts of the country. ACRE should also consider meeting in public.

— *There should be clarification of financial liability in the UK.*

28. In the absence of specific provision in Directive 90/220, it is left to individual countries' legal systems how far compensation would be available for damage caused by GMOs. The Environmental Protection Act 1990 provides that if damage is the result of the law being breached, and remedy is possible, steps may be taken to remedy the damage and recover costs. However, to our reading, this relies on a successful prosecution being brought. The civil liability situation is also unclear—a key defence in civil liability for environmental damage is whether the damage was “reasonably foreseeable”—which it may not be for damage caused by a GMO. In our view, a form of strict liability is appropriate, and if agreement cannot be reached on this at European level it should be considered how it can be applied at UK level.

3. *The most appropriate jurisdictions for decisions on genetically modified organisms*

— *The UK Government must consider how to cater for the wide range of concerns articulated in relation to GMOs, consider innovative institutional arrangements, and involve a wider spectrum of people in the decision-making process.*

29. A wide range of concerns has been brought forward about the application of GMO technology. These include ecological concerns and the cumulative impact of GMOs on biological diversity; concerns about the future direction of agriculture and whether GM technology will or will not contribute to more “sustainable” practice of agriculture; health concerns from the growing and consumption of GM crops; concerns that consumer choice is being progressively eroded by global trade in agricultural products and the unsegregated presence of GMOs in those products; scepticism about the benefits of the technology and concern that it should be justified in social terms; concerns about the ethical implications of transferring genes between species; concerns about the domination of agriculture by a few very large companies.

30. Most of these concerns have been at some time laid at the door of the systems for scrutinising the environmental and food safety of GMOs, and these systems are not designed to deal with most of them. At the same time, trust in official processes of risk assessment and decision-making has been eroded by other crises over food. The net effect is a sense that the regulatory and policy machinery is unresponsive to people's concerns about GMOs, both nationally and internationally. Worse, it is on some issues, such as segregation, powerless to intervene in the practice of global trade in agricultural products.

31. This situation requires innovative solutions. As a first step towards this, we recommend the formation of a working group, with representation from a wide range of interest groups, to look at the technology “in the round” and recommend appropriate forms of control. Such a group could build on the work of the Nuffield Council on Bioethics, which is currently examining the issues around GM plants, and which is due to report in 1999.

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Examination of Witness

MISS JULIE HILL, Programmes Adviser, the Green Alliance, called in and examined.

Chairman

188. Good morning, Miss Hill. Thank you very much indeed for coming to give evidence to the sub-Committee, to help us with our enquiry into genetic modification in agriculture. You are, as I understand it, a member of ACRE, but I wonder whether I could ask you to introduce the Green Alliance. We know something about it from the paper you sent us. Could you say what the origins of Green Alliance are and how

it comes to have the title of Green Alliance. What is its history of involvement in this particular matter?

(Miss Hill) Of course. The Green Alliance is an environmental charity or non-government organisation: NGO, to use the usual jargon. The Green Alliance was formed in 1978 with the purpose of influencing all the political parties to have an environmental agenda. So it was formed explicitly to be cross-party, not affiliated to the Green Party or any one particular party, but to try and

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elevate the position of the environment on the political agenda generally. I think, 20 years ago, the position of the environment was fairly low on the political agenda and that was a specific job which needed to be done. The original Green Alliance: the alliance referred to an alliance of individual people, eminent in a range of fields—including scientists, politicians, media people—people who had some standing in public life and who were willing to lend their name to the cause of elevating the environment on the public agenda. So that was the alliance. We are not, in a formal sense, an alliance of other environmental groups; but in an informal sense we do a lot of work with the other major environmental groups including Greenpeace, Friends of the Earth, World Wildlife Fund for Nature, the RSPB, the CPRE. We have very strong links with them and on quite a number of topics, including this one, we act as informal liaison and co-ordination for those groups. However, they are not formally signed up to us in any mandated sense. Our history of involvement in this issue: we came across it first in 1987. The Royal Commission on Environmental Pollution was doing an enquiry on the possibility of regulating biotechnology. Also, the European Directives were going through their processes at the time. We helped host a visit for a United States campaigner, Jeremy Rifkin, on this subject, as a way of raising the awareness of the environmental implications of genetic modification in the United Kingdom. Subsequent to that, we felt it was a subject we should continue looking at, (the policy development), partly because there were not many other NGOs strongly interested at that time; but partly because it fitted very well with Green Alliance's skills in terms of looking at regulatory process and administrative process, which has always been part of our particular expertise. So we did quite a lot of work on the Environment Protection Act 1990, Part VI of which implements the EC Directives. That was going through Parliament. Shortly after that I was asked to join the Advisory Committee on Releases into the Environment, which was formed in 1990, as the Statutory Committee which advises the Secretary of State for the Environment and others on the implementation of the law. I should stress that I speak, of course, for Green Alliance in this context. I cannot speak for the Committee. I do not speak as a member of the Committee in this context, but a lot of my experience is drawn from those deliberations. Thankfully, I think enough of them are public and have been analysed academically and politically for me to be able to say quite a lot of how the regulatory process works, without that being a special privilege from my being involved in the Committee.

Chairman] Thank you very much. Perhaps we can proceed to the Green Alliance's views. Lord Gallacher.

Lord Gallacher

189. Ms Hill, do you think that on balance GM crops will have a harmful or beneficial effect on the environment?

A. I do not think we are in any position to make that judgment at the moment. One of the reasons for that is because to make that judgment we will be

weighing up very different kinds of environmental impacts. There are the ecological impacts of the movement of genes. There are the possible environmental impacts of the use of chemicals. There are the possible environmental impacts of changes of land use. We do not know enough about those three types of impacts, about how they will progress in the long-term, to make any kind of judgment on that yet.

190. Has your organisation made any attempt to assess a timescale when such a judgment could be made?

A. No, not a timescale when we can make the judgment. We are continually asking for information which I hope will help us eventually to come to that kind of view. Our message is that there should be full environmental audit of this technology so that we can come to a judgment. Our main problem is finding an acceptable way of weighing up those different kinds of things. Some people are very concerned about the concept of genetic pollution in itself. Others may be more concerned about the use of chemicals. There are such different kinds of things that it seems to me that we have to have a politically acceptable way of assessing them, and deciding whether they can be balanced against each other or not.

Chairman

191. Paragraph 5 of your paper seems to me to strike quite a sceptical tone in this matter. You say that the biological companies are arguing that the GM crops "will lead to a decrease in the use of damaging pesticides, but as yet they have provided very little independent evidence that this is the case." Would you say you were sceptical about these claims, or are you neutral on them? Would you be interested in knowing whether they are correct or not?

A. I am certainly interested to know whether they are correct. I am presently sceptical because we have seen very little independently assessed evidence that takes into account all the factors I have just mentioned. Also we have had hardly any commercialisation of GM crops yet and some of these things are quite hard to assess except on quite a large scale of growth. It is very early to have evidence, but my feeling is that the data that does exist has not been collected in a way that is going to give us a great deal of intelligence about these issues.

192. And an environmental audit would be a means of collecting this evidence?

A. Yes. There needs to be an agreed approach to judging the environmental impact that takes into account the wide range of issues.

Lord Moran

193. Could you tell us how you think the indirect effect of genetically modified crops on biological diversity should be taken into account in the regulatory process, both at national level and at community level.

A. The first step is making it explicit that indirect effects should be taken into account. The interpretation of damage to the environment should include indirect

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[Lord Moran *Contd*]

forms of damage. Both the Directive and the United Kingdom laws are actually quite broadly framed, but in both there is a fairly narrow interpretation of what constitutes environmental harm, which has been arrived at through the process of implementing the Directives. That could be reversed. The draft revision of the Directive is on the table at the moment and has wording which says that indirect effects, short and long-term effects, should be taken into account. In a way, it is a simple matter of making that explicit and providing some guidance about what those indirect effects are. Again, I think that is relatively straightforward. Indirect effects may be the effects of any chemical used in conjunction with the crop. There are the effects on target and non-target species of plants and animals; the likely cumulative effects of the crop being grown on a commercial scale; the likelihood of resistances evolving, and possible changes in land use pattern. All these things could be assessed if you gathered the right kind of data. They could be assessed and judged.

194. You think the draft Directive is satisfactory, from your point of view, on this?

A. It is a beginning. I would not say it is satisfactory in terms of providing guidance for Member States on how to do it. It is a beginning that the language is there, that could lead to an agreement that this an important part to consider the indirect effects, but there needs to be much, much more in terms of detailed guidance about what it is the Member States are meant to look at when they make their assessments.

Chairman

195. At national level. Is this something which should be incorporated into a change to the remit of the existing committees, or should there be a new body?

A. It would be most effective to change the remit of the existing committee, yes.

Lord Wade of Chorlton

196. Before I ask my question, could I ask a question which follows on from Lord Moran. When you talk about these indirect effects, what is your view on the balance between what might be, on the one hand, from an environmental point of view, to be a not good effect; but from another point of view, the use of the GM products which could bring enormous benefits. Where do you put the balance? Is there a balance, in your mind, or in the view of the Green Alliance, or is there no balance? Is it that if it is against the environment it is wrong and you do not do it? Or do you think there might be certain areas where we have to sacrifice environmental changes in order to achieve certain other benefits, as we have done since time began.

A. I am not sure it is for us to make those judgments, especially when neither the environmental harm nor the other benefits are very clear.

197. So how would you make the judgment?

A. I think that belongs in the political realm. We have international biological diversity objectives. We have, as a society and as a nation, signed up to fairly strong objectives protecting biological diversity across the world. In that sense we have, as our objective, protection of the environment.

198. We also have an objective to improve the benefits to the whole world: to make less people starving, to create more food opportunities, to create jobs and industrial development, to improve the economic needs of the people. These are also very strong objectives.

A. Indeed, and in the end Governments and Cabinets make those decisions but we have an environmental——

199. What would be your view?

A. Well, as I said earlier, I do not think we are in any position to judge the relative balance between those things. As an environmental organisation, our concern is that there is not environmental harm. That we do our best to protect the environment and that we take a precautionary approach. My view is that there is no point in accruing other benefits if they are not sustainable. It is all very well to say there may be benefits in terms of food production, but if they are not environmentally sustainable they will be benefits which will be short-lived, so I do not think there is much point in that. Economic benefits, no-one can deny the need for, but we can derive economic benefit from a great number of things other than GM technology. Therefore, our primary concern is that this technology does not carry unnecessary burden on the environment.

200. May I move on to my question which looks at the question of monitoring, particularly the monitoring of GM crops after commercial consent. This is something that you argue for. How do you see this actually happening in practice? What would you be monitoring, measuring? How would you set the standards of measurement that allowed you to decide that it was a good thing or a bad thing?

A. The key principle of monitoring is that we should be able to revisit the key assumptions made in risk assessments when a crop is given commercial consent. At the moment, the few crops which have been given commercial consent are going ahead on the basis that we have a certain level of confidence that they will only cross-hybridise with wild relatives at a certain rate, or the genes will only persist in volunteer populations of the crop at a certain level. Now, all of those are assumptions based on a body of scientific knowledge about natural selection and the movement of genes. They are not judgments based on any kind of empirical data on the large-scale growing of this kind of crop, precisely because they have not been cleared for commercial use before. So we are assuming certain things will hold true when these crops are grown on a large scale, based on key scientific assumptions and a small set of empirical data from field trials. Now, it seems to me sensible that when crops are grown on a commercial scale, to revisit those assumptions to see if they hold true. Things like

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[Continued]

[Lord Wade of Chorlton *Contd*]

hybridisation with wild relatives and persistence of genes are measurable. It is difficult to set up the experimental protocols which would do that measuring accurately and to people's satisfaction but it is not impossible, in my view. We should be able to come to an agreement between the scientific community, the industrial community and the organisations who have an interest in the environmental impacts, on actually what we should measure: what is important and how to do it. I do not have ready answers to that as yet. The Green Alliance is organising a workshop later on this year with scientists and with non-government groups to discuss precisely that: what could be feasibly and usefully measured? We must make some effort to check our assumptions. Otherwise, it is like conducting a huge uncontrolled experiment without any means of checking the result.

201. Who do you think would be responsible for doing this and where would the cost fall?

A. That is also a matter for considerable debate. I think there is probably a mixture of responsibility for Government, for the industrial interests, and possibly also for the farming community. When I say "responsibility" I do not just mean cost responsibility but broad responsibility. I do not want to prejudge that. I hope we can find some feasible agreement on that; about what is the right allocation of responsibility.

Lord Gisborough

202. Is there a role for Government in requiring or assisting the segregation of GM products down the food chain?

A. I should stress that our primary interest is environmental rather than food and consumer choice. Nonetheless, I do believe in consumer choice. I am not sure our Government could unilaterally require segregation of crops coming in from abroad but I think it should certainly encourage it. On a United Kingdom basis, our Government should at least require traceability which is a first step towards segregation. What I mean by that is that it should be a requirement to record where GM crops are grown. That kind of traceability would enable segregation by growers and processors and retailers, if they wanted it, but would also enable environmental traceability, if you like. If we are going to go in for any meaningful monitoring, at least we have to know where GM crops are being grown.

Chairman

203. Is that feasible internationally or only within a single country?

A. I think it is only feasible internationally if individual countries are prepared to require it, or if agreement can be gained at a European level to ensure monitoring. Obviously, ideally, in most of my comments it is implied that we would be doing this across Europe. We would be improving the control of the technology across Europe, but in the absence of agreement in Europe I am sure the United Kingdom Government can take steps here.

Lord Rathcavan

204. Miss Hill, you appear to be satisfied with the transparency of the operation of United Kingdom regulation, although not with the degree of public awareness. In your note, in paragraph 13, you welcome some of the new moves made in Europe, but you indicate that in Europe also you would like to see greater transparency. What further changes would you like to see?

A. The draft revision of the Directive does put in place some better provisions for public access to information. Previously, it only required a very small set of information to be released by each Member State and, therefore, the extent to which Member States did provide information varied enormously from quite a lot in the United Kingdom and Netherlands, to almost none in some other countries. The recent revision allows for the Commission itself to provide summaries of applications for marketing consents, which are clearly the ones that tend to attract the most interest, but they are only proposing to allow 30 days for comment which is probably, on the United Kingdom experience, not long enough. Something like 60 days would be more realistic. There is also a new provision for assessment reports, which is a kind of summary evaluation of an application for marketing made by the Member State competent authority to which the application is first made. Our disappointment about that is that the Commission is only proposing to release the assessment reports after a decision has been made, which I think is definitely unhelpful. In fact, it is almost less helpful than not releasing any information at all, for people to feel that they can only get something once a judgment is finalised. My other anxiety about the Brussels system is the increasing use of central scientific advice. There are now committees set up in Brussels, under the auspices of DG XXIV, which have been called upon, in effect, to be the final arbiters on applications for marketing consents, where there have been disputes between Member States as to whether they should go ahead. This to me is damaging to the democratic accountability of the EU system, because each application goes through a scientific evaluation process in the Member State which is, at least to some extent, (certainly in the United Kingdom), accessible in the sense that one can see when the application is coming up for discussion. This is because agendas are published now. One would be able to get reports of the meetings and obtain copies of the dossiers from the Public Register. It seems to me, for the Brussels-based committees, that this is much further removed. One could pay a lot of attention to the scientific judgment process in the United Kingdom, for instance, and then a completely different judgment is made in Brussels. It seems, as yet, very unclear whether those committees are designed simply to resolve disputes and are, therefore, somehow meant to be the final port of call for an application; or whether they are actually going to re-rehearse all the evidence and have a completely different scientific judgment, (and a completely different scientific discussion possibly). In that sense, it seems unclear to me how accountable that system is. It is actually

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[Lord Rathcavan *Contd*]

reasonably transparent, to some extent, because you can find out what the committee's deliberations were on the web site after the meeting—in some cases, I gather, even before the members themselves have seen it or have cleared the minutes, which again is slightly worrying. However, in terms of its accountability—the access to those committees, who is on them, how are they formed, what kind of job are they doing—I have anxieties as to whether this is operating in the public interest of the citizens of Europe.

Chairman

205. The composition is not transparent? Is that one of your criticisms?

A. The members of the committees are appointed, it seems, simply by their volunteering to sit on the committee. But it is very difficult for outside parties to influence an essentially Brussels-based committee. It is certainly less easy to influence or to understand its operation and to put views into it than it is if you have a committee sitting in your own country, where you can begin to build up at least some kind of familiarity with how the committee is working.

206. But how otherwise should the Commission deal with failure to reach agreement in council?

A. I think there should be every effort to resolve it between the Member States. If the problems are predominantly political, which is what they are; they are disputes about the acceptability of certain risks and not the scale of certain risks. That has been the nature of the disputes. Therefore, recourse to another body of scientists is not in our case going to solve that kind of problem. It simply adds up to a yes/no judgment which, anyone who has objected to beforehand, is unlikely to have confidence in.

207. But at least if it results in a decision, if you did not have them there would be even fewer decisions.

A. I am sorry?

208. If it results in a decision which you might otherwise not get.

A. Certainly the present system has not succeeded in resolving disputes, largely because the interpretation of the Directive, as we were discussing earlier, has been different in different Member States. The reason for the disputes is that some Member States object to applications because they feel the right things have not been taken into account. Those problems are only resolvable by expanding the scope, or at least thrashing out an agreement as to what the scope of the Directive should be. They are, if you like, a protest about the nature of the decision-making process, as much as they are about objections to an individual application. It seems to me that recourse to another set of scientific committees, without clearly the job to resolve that kind of problem, is not going to improve the situation.

Lord Gallacher

209. Is there any body at the European Union level, operating with similar aspirations and organisation functions to your own, which could

represent the opinions you hold when matters of dispute appear simply to be about to be resolved on a yes or no basis in Brussels?

A. There is, and I am sure they do. There is the international organisation of Friends of the Earth which is called CEAT, which is a French acronym, which operates in Brussels for international NGOs. They do, of course, monitor the way that the scientific committees are working.

210. Would you say that it is fully active in this area?

A. It is hard to say what "fully" means. As I was saying, I feel that the problem is not just the inability to access those committees if they were doing the right kind of job. It is that they are not doing the right kind of job.

Lord Wade of Chorlton

211. I am still rather confused by this. Basically what you are saying, as I understand it, is that the views on these issues are very diverse. A lot of them are based on emotion rather than upon scientific fact. It is where people come from and how they see these issues, which is dramatically differently. We are aware of that. You are saying that because of this, the present system is not satisfactory. Whatever system you have, how do you actually deal with that issue, when the scientists can say, "These are the actual facts of the case and we see it from a scientific point of view"; but other groups in society can see it from an entirely different point of view. I do not quite see how you say that is a problem with the present system of decision making. How do you resolve any other system of decision making that takes those two extremes, (or may well turn to extremes)? The point I was talking to you about earlier, that clearly there is a view on the economic issue. Many groups in society put the economic needs before certain environmental needs. You said to me, in answer to that question, that this is a political decision and has to be taken from a political point of view. Are you saying then that we set up political committees, which ultimately make the decisions, yes or no, because decisions have to be taken?

A. Let me be clear about what I was saying about the possible inadequacy of the scientific committees in the situation of dispute between Member States on applications. The two things going on there are the nature of the scientific advice on the possible effects of each application, and whether that is accessible and accountable, and the fact that some Member States want different kinds of environmental impact taken into account. So it is not even about those broader issues you were talking about, about where the social or economic benefits are judged. It is simply a dispute about what is the interpretation of environmental harm in this context. Some Member States, notably Denmark, Austria—and Norway when there was a time when they were likely to join the European Community—when the first application for commercial consent went through, the PGS oil seed rape, there were very strong representations by those

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[Continued]

[Lord Wade of Chorlton *Contd*]

countries that part of the evaluation should be the effects of the herbicide used in conjunction with the crop. That was the root cause of the very long dispute within the Community about whether that particular crop should be allowed through. That seems to me the kind of dispute you can only resolve by talking to countries about it: is there a resolution in terms of taking those effects into account, or will they agree to drop that consideration for this particular application but have it brought in for future ones? Do you see what I mean? That particular point of contention is not something you can solve by going to another scientific committee and saying, "Is this a good thing or not?"

212. I accept that. What I am asking is, what decision-making process do you establish if you accept that there are different views, different priorities, in coming to the right decision? Ultimately, decisions have to be made. What I am asking you is what kind of process do you believe could make decisions and be seen to be effective and people would respect the decision?

A. The process should come out of the revision of the present Directive—which I think should seek to expand the scope of the Directive so that it clearly takes into account all the possible environmental effects of growing GM crops—I am not proposing that the regulatory system embraces issues of need and benefit at this stage. I personally think it is very difficult to do that. All I am asking is that it embraces all relevant environmental considerations. At the moment, there is serious dispute amongst European countries as to whether that is the case.

Lord Willoughby de Broke

213. Are you concerned at all, that the length of time of regulation of these matters which we have been talking about, is putting European companies to a disadvantage in relation to American companies—it is perhaps not your concern but you are aware of that—where the regulatory process seems to be much shorter?

A. The first comment I would make is that the regulatory process in America, in its principles, is surprisingly similar to Europe. Although people try to make them look as if they are very different, in practice I think in the way they seek to operate is very similar. The delays in Europe, as I was saying just now, have been due to the fact that Member States have not been able to agree upon how we should judge the adverse effects of some of these products. Therefore, the delays have not been endemic to the structure of the regulation. They have been a consequence of its aspiration, or rather the failure to spell out clearly what the aspiration is of the Directive; what the role is of the Directive; and how it should seek to protect the environment. It is not a failure of the fact that it has to go to each Member State, be cleared, and then sent back to the Commission or whatever. It is that in that process, people have found more and more issues which they feel they cannot deal with adequately, or that there is not agreement; or that when each Member State gets an application, they find

they look at it in a very different frame. That is where the delays and disputes have arisen. So, in that sense, the resolution has to be a political one through a process of revising the Directive to a more satisfactory state, where it more clearly and adequately deals with all these environmental issues. If that can be achieved, then things will be seen to be proceeding more smoothly. It may mean that some things do not get clearance. That has to be accepted. I hope we have the capability to say no to some of these developments. In that sense, I am sure our European industry will argue that it is a disadvantage, but I am afraid our primary interest is that there should not be environmental damage and that if we have to say no, we have to say no.

Lord Jopling

214. I confess I am a bit confused because you made various answers in which you were very critical of the centralised system of decision-making, yet I heard you say earlier with regard to segregation that you did not think the United Kingdom could do it alone, which implied to me that you felt that there should be a centralised arrangement. That brings me to the question: do you believe that the jurisdictions are about right as they are, or do you think there is a case for giving individual Member States greater latitude to go their own way, when it comes to the question of granting commercial consents?

A. The issue of segregation is a difficult one. If we are talking about segregation of what are globally traded commodity crops, it implies requiring American farmers or Canadian farmers or Brazilian farmers to segregate their crops before they are bulked up and shipped to this country. That is what I meant, I am not sure that our Government can require that. I do not see what the legal basis could be for doing that, other than banning the import of anything mixed. I cannot imagine that being acceptable under trade rules as they stand. There is a strong argument for looking at trade rules and the extent to which they could be developed to allow countries to say no to particular genetically modified foodstuffs or crops if they were felt to have a human or environmental threat. That actually should be possible under trade rules, at the moment, but you have to show a very clear and immediate threat as opposed to a less clear and possible long-term threat, so there is probably room for looking at trade rules. This is what I meant about the difficulty of unilateral action on globally traded commodities. In terms of jurisdiction over environmental impacts, there ought to be a lot more room for the United Kingdom Government to act. So that the United Kingdom Government can, for instance, put conditions on the way that crops are grown or the way they are managed in this country, to protect the environment. I think we have certainly got to look at doing that if we feel there is not satisfactory resolution in Europe. Ideally, there should be resolution of these environmental issues across Europe. This is because part of the reason why we have European environmental law is because the environment does not stop at political boundaries. We perhaps tend to forget that in our geographical

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[Lord Jopling *Contd*]

position, but for Continental Europe it seems a nonsense to have different environmental standards for countries who share basically the same landscape. For that reason, I think having a European Directive for environmental protection in this field is highly desirable. It is highly desirable that we get it to operate properly.

Lord Moran

215. As you will know, English Nature have called, with the support of the other statutory agencies, for a five-year moratorium on the growing of genetically modified crops, to allow time for the subject to be better researched and the regulatory system overhauled; possibly by increasing the remit and membership of the Advisory Committee on Releases into the Environment, in order to take a more comprehensive view on environmental effects. Do you support that call and do you think it is necessary to have this pause?

A. I think I am right in saying that they have only called for a moratorium on one crop, which is the PGS oil seed rape, but I cannot be absolutely confident about that. I think it would be a very good thing to have a pause. I personally voted against the commercial approval for the PGS oil seed rape in the ACRE Committee and that is a matter of public record. This is because I felt we could not be clear enough about the long-term potential of the crop to hybridise with wild relatives and what the long-term fate of the genes would be.

Lord Willoughby de Broke

216. Could you explain the problems which you have with current risk assessment and what differences there are between Member States. Is it wise that these risk assessments are conducted by the applicant and not by the competent authority?

A. The problems with risk assessment: the essential problem is the inability at present to look at indirect effects, which we have already discussed, so that the risk assessments tend to concentrate on the ecological impact of the possible movement of genes from a crop to volunteer populations of the crop, or to wild relatives. There is attraction to things like the possible impact of engineering insect resistant directly into a crop and how that may affect the surrounding environment. However, the wider knock-on effects, particularly the effects of chemical usage in conjunction with herbicide-tolerant crops, are at present left outside the risk assessments and that is a major failure. Another problem is the limitations of the case-by-case practice of risk assessment. I mentioned just now that risk assessment would look at something like an insecticide engineered directly into a plant, where the plant is expressing the toxin. A risk assessment would try to look at which insects that might affect; for instance, would there be non-target as well as target species affected? One of the problems of a case-by-case approach is trying to get a view of those effects on a cumulative and additive scale. You can maybe do it on one crop, in one particular

management context, but it is very difficult to ask the question: what happens when a large range of crops, in a large range of situations, have that kind of engineered toxin? What might be the overall impacts on the insect populations? It is a question of the cumulative impacts of using that crop as part of agricultural strategy. It may well be that this is not something you can deal with in individual risk assessments, but individual risk assessments should certainly give us the clue to look at it on a much broader basis. So it is the ability to look forward and be strategic that we lack, I think. You can do an individual risk assessment in the light of what has gone before, but it is very hard to do it in the light of what will come ahead. Another problem for the risk assessment system, as we have it, is that we do not have a clear interpretation of what is harm to the environment. The Act deliberately avoids it, to avoid pinning something down to which one could then see exceptions. It is deliberately broad. The problem with that is that it has tended to be narrowly construed and we do not have a clear view of what is an acceptable impact on the environment. The example we had just now of the PGS oil seed rape, the risk assessment on that, when it was given approval for commercial use it was assumed that there would be some hybridisation with wild relatives, but the judgment was made that it would be on a scale which was not a problem. I do not think that is the kind of judgment which commands widespread acceptance at the moment. A lot of people find that prospect alarming, or would say it is unmeasurable and contains too large a degree of uncertainty, really to base a definitive judgment of risk on the kind of data we have. So that is another problem. We have contention about what is an appropriate interpretation of environmental damage from this kind of technology. Your question about what is the difference between Member States: as I mentioned earlier, one of the primary differences has tended to be the extent to which indirect effects are taken into account. There is a quite helpful document that was produced for the Science and Technology Options Assessments Panel of the European Parliament, which is called *An Appraisal of the Working and Practice of Directive 90/220/EEC*, on deliberate release of GMOs, by Rene von Shomberg. That sets out, in some very helpful tables, the different views and disputes between some of the Member States about the operation of the Directive. Your point about: is it a problem if the risk assessment is undertaken by the applicant? I do not think it is a problem if the competent authority which judges that risk assessment is in a position to challenge the data submitted and the conclusions drawn from it. My impression of the way the process works in this country is that the officials who prepare the applications for the ACRE Committee consideration, go through them in extremely thorough detail and check that all the relevant questions have been addressed and that the right information is there. Also, they check that the conclusions are supported by the data and that nothing has been claimed as commercial in confidence if the applicant cannot justify that. A great deal of work is done to make sure that the

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applications are thorough. All that correspondence goes on the Public Register so it is possible to see what kind of backwards and forwards process has been undertaken. What is more important is that we are asking the right questions and making the right judgments. As I said earlier, one of the problems is that there are large degrees of uncertainties built in, in any judgments, about the environmental impact of genetic technology. It is very important, in looking at risk assessments, that we are clear where those areas of uncertainty lie and what we are judging to be an acceptable level of uncertainty. That is what a lot of outside commentators have a problem with. There seems to be an end result that makes it look as if lack of evidence of risk is actually evidence of safety. Those are not the same things. We have to be explicit about uncertainty. This is one of my major concerns about our system of having an applicant do a risk assessment and then having that judged by the committee. Perhaps both parties know what the uncertainties are but they are not drawn out very explicitly.

Lord Grantchester

217. Do you want the companies to take the decision themselves on assessing these risks within the committees? Do you think the committees could actually test these risks and have a legitimate extension of the regulatory framework? Could they actually test these risks if you are then assessing them as being beyond the scope?

A. I am sorry, would you mind repeating the question. I did not quite catch it.

A. You talked a lot about risk assessment and undertaking risk assessment before things go ahead. The question is whether the company wanting to undertake any genetic experiment can actually test the risk you are assessing. You say this is an unacceptable risk. Can the company then go out and test that risk?

A. So can there be adequate data on whether something is dangerous or not? Is that what you are saying?

218. You are making a risk assessment to say that we think this is an unwise experiment or test because of X, Y or Z. I am asking you, could the company challenge your risk assessment and do the test, as to whether there will, for example, be cross-pollination into the wild environment?

A. The problem is that a lot of the issues, which are being put forward as possible risks and being judged, are ones which it is almost impossible to empirically test. To give you an example of hybridisation with wild relatives of an oil seed rape crop. Most risk assessment tends to be based on whether it has been possible to almost forcibly cross oil seed rape with possibly compatible species in laboratory conditions. To begin with, it was said that this had hardly ever been observed in the field. As time has gone on, various researchers have observed particular hybridisations in the field, and some have been quite surprised by the fact that they have been able to observe them and observe them at a greater

rate than was thought possible. That is the sort of thing which is only possible when the experiments or the commercial growing is done on a very fairly large scale. This is the point about what scale of release do you sanction, in order to get that kind of data before it presents itself as an unacceptable risk? This is my point about looking at the issues after commercialisation. With some crops it would be impossible to come to any very definitive answers about how far things like cross-hybridisation are going to occur. It may well be quite proper to judge that it is unlikely that they will occur at a scale that causes us real problem. Certainly, it will not happen quickly but we should be monitoring to make sure that is the case. In a way, you have an on-going risk assessment on that kind of issue. There are other issues to which you might quite properly say we do not have enough information and, therefore, nothing should go ahead. Under that category you possibly have things like work with virus resistance, where we have very little information about the possibility of recombination of viruses, for instance. That may be the kind of work which is too risky to take to a commercial scale. It is very hard to quantify the extent to which it might be possible to create a new plant virus. I really think it differs with the crop which is under consideration and the scale at which it is being used at the time.

Chairman

219. You call, in your paper, for clarification on the subject of liability of damage caused by GM crops. Does your Alliance have views on that subject as to what the liability should be?

A. Yes. Personally, I think there should be strict and retrospective liability for damage from GMOs. We have advocated that for other forms of environmental damage. It is even more important in this field.

Lord Grantchester

220. How far should the risk assessment come after the experiment, which was the point I was trying to bring out in my question. Obviously there is the fact that you do not really learn a lot unless you are prepared to take risks. If you say "de-risk", companies are not really going to make great strides forward in learning. This brings me on to the question of responsibility of companies. What, in your view, are the responsibilities of companies developing genetically modified crops, and should they have a wider responsibility other than just trying to find out scientifically the effects of the experiment?

A. Yes, I think they should. I would say they have responsibility to consult stakeholders. For this technology there is a very wide range and very large number of stakeholders. Companies developing these crops are effectively asking the entire consuming population to eat the food that results from them. They are also asking all of us, possibly, to bear a certain degree of environmental risk. In that sense, the earlier they address those kinds of concerns and talk to interested parties about the concerns and the priorities people have, the more chance they have of developing

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[Lord Grantchester *Contd*]

products which do have clear benefits and do not present risks.

Lord Redesdale

221. There is a growing body of concern about the risks that GM food is putting forward, but most GM food is grown in the United States at the moment. Why has there been such a different reaction between European consumers and American consumers?

A. I do not know in detail. I do not think anyone can know really. I can make two conjectures. One is that the United States has not suffered the same crises of confidence about the handling of food risk that we have in Europe. Everyone hates the analogy with BSE but let me make it clear what the analogy is. The analogy is not one of a similar type of risk necessarily. It is an analogy about the political handling of risks that are hard to quantify. The fact that the politicians were willing to say "it is safe" when they had no basis for doing so. The fact that they were prepared to attribute responsibility for the problems to their scientific advisers, which I think is entirely unfair. In that sense there is an analogy with GMOs. Consumers are wondering, "Well, they told us it was safe last time, does this apply here? How can we be confident that the right relationship is established between the

scientific advice and political judgments on that scientific advice?" So maybe the United States has not suffered quite that kind of crisis of confidence on that level. The other conjecture is that the United States has rather more natural environment left than we do. Most of the United Kingdom environment is either semi-agricultural or, in fact, fully agricultural. A lot of our remaining precious landscapes and small pockets of biodiversity are embedded in that agricultural and semi-agricultural landscape. In that sense it is possible that GMO crops could have a disproportionate effect on what is left of our biological diversity. That is not true in the United States because they very sensibly fenced off large areas of wilderness so that they are untouchable. They are, however, engineering native species to be genetically modified and I think that is a huge risk. I do not know why American consumers are not more concerned about that.

Chairman

222. On that provocative note I think we will have to end. Thank you very much indeed for coming to give us your evidence.

A. You are welcome. Thank you, my Lord Chairman.

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Memorandum by Safeway Stores plc

SAFEWAY—BACKGROUND INFORMATION

1. Safeway is a major UK retailer with over 450 stores in the UK and an own-brand product portfolio numbering over 12,000 products. In 1997 the business achieved group sales of £7.5 billion, with the Safeway brand accounting for over 40 per cent of products sold. It employs over 76,000 people in the UK, with a significant central technical resource whose sole responsibility is the management of all technical aspects of the Safeway brand. The development of new and innovative products and services is core to the competitiveness of Safeway, and is in direct response to consumer demand. Safeways' investment in a dedicated Research and Development Team to research new products and processes and develop main Board-approved corporate policy has benefits not only for the company, but for the seven million customers who choose to shop at Safeway every week.

SAFEWAY PUREE PRODUCED FROM GENETICALLY MODIFIED TOMATOES

2. In February 1996, and in conjunction with Sainsbury's, Safeway became the first UK Food retailer to successfully launch a genetically modified (GM) whole food product in the form of Safeway puree produced from genetically modified tomatoes. Safeway has since sold over 600,000 cans of the product, with the genetically modified version outselling its conventional counterpart in some stores. *Key elements of the products success have been choice, customer benefit and information.* The benefits obtained through genetic modification in harvesting flexibility and reduced wastage during transport and processing were translated into direct consumer benefit by offering the 170g tin of the GM puree at the same price as a 142g tin of puree produced from conventional tomatoes. Customer choice was maintained by ensuring that in all stores the genetically modified puree was sold alongside its conventional counterpart, with information provided through clear product labels, shelf edge barker tickets and customer Help and Advice leaflets (Appendix 1). A trained customer services careline answered any further questions customers had.

SAFEWAY POSITION ON GENETIC MODIFICATION

3. Genetically modified foods are currently in the early stages of development and introduction to the marketplace. Safeway will consider the sale of foods (or foods containing ingredients), arising from the application of genetic modification, provided they have *approval* from the appropriate regulatory authorities and they *benefit* the consumer and/or the environment. Safeway views the development of GM products with direct consumer benefit as a positive step in building consumer familiarity and understanding. Current consumer confusion over genetically modified foods may be a result of the technology being applied in products which are traditionally transparent and unfamiliar to consumers such as soya. There is often confusion over what is possible using genetic modification, and which products are in development or have actually been commercialized. In this respect Safeway is absolutely clear, and can state that it has no plans to sell genetically modified foods containing genes of animal or human origin.

4. Safeway is firmly committed to working with its suppliers and stakeholder groups to develop sustainable farming systems which conserve and enhance the environment, whilst allowing the economic production of safe and wholesome food. In this respect we are encouraging the adoption of Integrated Crop Management (ICM) techniques through our support of initiatives such as the Assured Produce Scheme in the UK, and through chairing EUREP, a pan-European retail group which seeks to develop similar systems for overseas production. Safeway believes that biotechnology may have a significant role to play in providing farmers with the resources they require to continue to produce safe and wholesome food with minimal impact on the environment. In addition, genetically modified crops with traits such as drought tolerance or disease resistance may open new opportunities for overseas producers to satisfy not only internal demand, but earn valuable export revenue. Significant opportunities also exist in the development of "industrial crops" to produce raw materials normally derived from industrial synthetic processes. Such crops could both lower production costs and benefit the environment by producing products that are more closely tailored to the needs of industry without the need for further processing. It could therefore be considered important that subject to careful review, approval and control, European producers and associated industry should have free access to the benefits arising from genetic modification as an important component of their future resource base for crop production and management.

5. The introduction of genetically modified *commodity crops*, such as soya without segregation, has compromised consumers' rights to choose. In addition, the co-mingling of conventional and genetically modified commodity crops has run contrary to our strategy of controlling product quality and assuring product safety by developing systems for traceability. Safeway in conjunction with other UK retailers has lobbied US agribusiness on the importance of *segregation*, and continues to work with everyone in the supply chain to address the issue of choice on behalf of our customers. Recent work in conjunction with suppliers has resulted in the increased availability of small quantities of segregated "identity-preserved" conventional soya and soya ingredients.

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Certain suppliers are using these in the manufacture of some Safeway brand products to address the issue of consumer choice. Our customer Help and Advice *leaflet* (Appendix 2) covering GM commodity crops has been available in all stores since 1997.

APPROPRIATENESS AND IMPACT OF CURRENT REGULATION

6. The UK is generally acknowledged as having led the way in Europe in developing an objective and rigorous process for the regulation of genetically modified crops through the Advisory Committee on Releases into the Environment (ACRE), and the review and approval of genetically modified foods through the advisory Committee on Novel Foods and Processes (ACNFP). This view is supported by the large number of submissions received by the ACNFP in particular for review by organisations wishing to place the products of genetic modification on the market under the current EU review procedures.

7. Safeway has however been concerned by protracted negotiations over the regulations governing the labelling of genetically modified foods and food ingredients. The importance of clear, concise and consistent labelling in building consumer confidence should not be underestimated. The delay in agreeing pan-European regulations on labelling has only served to fuel consumer concerns over the use of genetically modified ingredients and increase the chance of market fragmentation, as individual EC member states formulate their own guidelines on labelling, and manufacturers and retailers seek to position themselves to minimize business risk in the resultant regulatory vacuum. In such a climate there is a greater chance of views being formed in the absence of objective fact, with the result that businesses act to remove genetically modified foods and ingredients from their products. To help bring increased objectivity to this area, Safeway would welcome a fresh and open public debate on the role of genetic modification in agriculture and food. Against this background, UK retailers and manufacturers have worked together over the past two years through the Institute of Grocery Distribution to develop voluntary guidelines on the labelling of genetically modified foods and ingredients. These were activated in January when UK retailers and manufacturers started to label their products on a voluntary basis, and in the absence of an agreed EC regulation. However, in spite of the recent agreement reached on labelling at European level, certain specific points on the labelling of key ingredients remain to be clarified. This piecemeal approach to regulation remains a concern to retailers and the wider industry, and only serves to breed confusion and uncertainty for smaller businesses which lack the resource of larger organisations to see the way ahead. In helping to develop consumer understanding of the new labels which are appearing on products, Safeway is issuing a further Help and Advice *leaflet* (Appendix 3) which will shortly appear in all Safeway stores at the customer services desk.

8. The effect of European regulatory process lagging that of the USA is starting to impact on industry at a number of different levels. In a market where commodities for use in food manufacture are traded on an international basis, this has the potential to cause problems for EU importers and US exporters. For retailers and manufacturers, significant effort is being expended on managing the issue, where the same resource would be better employed developing quality systems for traceability and segregation.

9. Safeway strongly supports efforts by the UK regulators to investigate the potential for post-release monitoring of genetically modified crops in the environment and in the food chain. We view this as an important component of the regulatory system, providing valuable feedback on the performance of genetically modified crops in the field.

FUTURE PROSPECTS

10. Recent indecision and protracted debate over regulation is likely to have a lasting adverse impact on the future acceptance and market uptake of genetically modified crops. Long-term business strategy is continuing to be moulded by current market uncertainty and consumer confusion over genetically modified foods. Until recently, the lack of a coherent and agreed regulation has sent mixed signals to companies looking to invest in this area. In parallel, many companies are unlikely to risk their businesses by embracing a technology where regulation is evolving piecemeal and public understanding and acceptance patchy. What is clear is that the Food Standards Agency has an opportunity to increase transparency and bolster confidence in the regulatory process. Safeway has already provided written comment of the role of the Food Standards Agency, and would welcome any attempt to increase and develop these principles further.

APPENDIX 1

A GUIDE TO . . . SAFEWAY DOUBLE CONCENTRATED TOMATO PUREE PRODUCED FROM GENETICALLY MODIFIED TOMATOES

In selected stores Safeway is selling tomato puree produced from genetically modified tomatoes (170g tins only). This leaflet has been produced to explain more about the product and the benefits it brings.

*17 June 1998]**[Continued]***IMPROVED FOODS**

Ever since farming began, man has looked for ways of producing and growing new and improved crops, selecting those with the best characteristics to produce the wide range of foods available today. Biotechnology is the term we use to describe these processes of selection and crossing to improve our food, and many of the foods we enjoy and take for granted are, in fact, the result of biotechnology. Products such as beer, cheese, salami, pickles, yogurt, soy sauce, bread, vinegar, wine and cider all rely on the processes of traditional biotechnology.

NEW TOMATO PUREE—WHAT ARE THE BENEFITS?

These traditional processes can be slow and somewhat hit and miss. For example, it can take flower breeders 10 or more years of trial and error to produce flowers with a particular petal colour. The processes of modern biotechnology which have been used to produce our new tomato puree go simply one stage further. Instead of a process of trial and error in developing new crops, scientists can now precisely identify individual genes and modify them. The use of genetic modification means that specific changes can be made to food crops, both quickly and precisely, without making other undesired changes. This was very difficult to achieve previously.

EXCELLENT TASTE, LESS WASTE

Scientists have now identified the gene that makes tomatoes turn soft during ripening, and they've also found a way of switching the gene off. This means that the tomatoes can be left to ripen on the plant until they have their full flavour and colour, while previously they would have been harvested earlier. These genetically modified tomatoes with the softening gene "switched off" remain firm after harvesting, providing greater flexibility during transport and handling, with reduced wastage. As less tomatoes go to waste, best use is made of water, a scarce commodity in California where the tomatoes are grown. In addition as the tomatoes contain less water, less energy is used during processing. Together, these improvements mean that Safeway's tomato puree, made from genetically modified tomatoes, is available at a reduced price in comparison to puree made from conventional tomatoes.

IS IT SAFE?

The law requires that foods produced using genetic modification are subject to extensive review and approval by a number of committees of independent experts who ensure that the strict guidelines and legislation in force are adhered to. The tomato puree produced from genetically modified tomatoes on sale in Safeway stores has been reviewed and approved for sale in the UK, and is perfectly safe to eat.

FOR MORE INFORMATION

Free leaflets which explain in more detail the processes of biotechnology and genetic modification are available from a number of organisations.

"Food for our Future—Food and Biotechnology" from:

External Relations
Food and Drink Federation
6 Catherine Street
London WC2B 5JJ
Tel 0171 836 2460

Fact Sheets from:

Institute of Grocery Distribution
Grange Lane, Letchmore Heath
Watford WD2 8DQ
Tel 01923 857141

"Genetic Modification and Food" reference no. PB2052, A MAFF "Foodsense" leaflet from:

MAFF Publications
London SE99 7TP
Tel 0645 556000

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APPENDIX 2

ADVICE ON . . . GENETIC MODIFICATION OF SOYA AND OTHER COMMODITY CROPS—WHAT IT MEANS TO YOU

Quite simply, genetic modification allows the improvement of crops by making precise changes with benefits for the consumer, farmer and the environment, achieving what previously took many years of selective breeding in a far shorter period of time.

This leaflet tells you:

- About commodity crops and how they are used.
- The benefits of genetic modification of these crops.
- The range of crops currently being developed.
- How their safety is ensured.
- When they may be used in Safeway products.
- How they will be identified.
- Where to get more information.

What are commodity crops and how are they used?

A commodity crop is one that is grown on a large scale and shipped in bulk, often internationally, before being processed for a specific use. Each year many millions of acres of commodity crops such as soya, maize and oilseed rape are harvested, traded internationally and processed into ingredients such as syrups, flours, oils and emulsifiers for use in a wide range of foods. In the case of soya, over 60 per cent of foods contain soya-based ingredients of one type or another.

What are the benefits of genetically modified commodity crops?

Genetic modification of crops such as soya can have benefits for both the farmer and the environment. Where previously the control of competing weeds was an ongoing problem for farmers, the newly developed varieties of genetically modified soya can be treated with a single all-purpose weed killer. This replaces the range of different chemicals previously used, killing only the weeds before breaking down quickly into harmless components.

What other genetically modified crops are currently being developed?

In addition to soya, other genetically modified crops including maize, oilseed rape and sugar beet are being developed. These have benefits such as improved resistance to pests, disease and tolerance to all-purpose weedkillers for improved weed control. Many farmers may decide to grow these new varieties where they offer significant benefits over conventional crops they have previously planted.

Are they safe to eat?

Yes. Before these new crops can be grown, harvested and processed for food, they must be reviewed by the relevant authorities in the UK, Europe or USA, and pass a rigorous assessment which in the UK includes scrutiny by independent experts.

When will Safeway products contain ingredients from these new crops?

From late 1996 some processed foods that we sell may include a small proportion of ingredients derived from the 1996 harvest of genetically modified crops.

Will they be labelled?

As the processed ingredients from crops currently being grown are no different in composition, nutrition and processing characteristics to those from the conventional crop, UK regulations state that they do not need to be specially labelled. However, Safeway recognises that some customers may still be concerned about eating foods

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containing ingredients from genetically modified crops. Information on the composition of Safeway brand products, including a list of products free from soya, can be obtained from Safeway Customer Services at the address below.

Where can I obtain further information?

Free leaflets which provide further information on genetically modified foods are available from the following sources:

Safeway Customer Services
Safeway Stores plc
Beddow Way
Aylesford
Kent ME20 7AT
Tel: 01622 712 000

The Soya Bean Information Centre
Russell Square
London WC1B 4HJ
Tel: 0345 023 288

External Relations
Food & Drink Federation
6 Catherine Street
London WC2B 5JJ
Tel: 0171 836 2460

APPENDIX 3

ADVICE ON . . . LABELLING OF GENETICALLY MODIFIED FOODS AND INGREDIENTS—WHAT IT MEANS TO YOU

Over the past few years, farmers in the major growing areas around the world have started to plant genetically modified (GM) commodity crops such as soya and maize for improved weed control and increased yield. In 1997, the first significant volumes of these crops were grown and harvested for processing into food ingredients such as soya and maize flours and oils, soya lecithin and maize syrup. For this reason, and in accordance with new legislation, we have started to label Safeway brand foods which contain ingredients processed from genetically modified soya and maize.

This leaflet explains:

- The reason for labelling genetically modified foods.
- What the new labelling will look like.
- What kinds of products will be labelled.
- When the new labels will start to appear on Safeway brand products.
- Whether foods carrying GM Labelling should be avoided.
- Where to get more information.

WHAT IS THE REASON FOR LABELLING GENETICALLY MODIFIED FOODS?

Safeway is committed to customer choice and clear, informative labelling. In common with other retailers, we have pressed for and continue to encourage the industry to segregate genetically modified and conventional crops. In parallel, we are labelling foods which contain ingredients from genetically modified crops to help our customers make informed purchasing decisions.

WHAT WILL THE NEW LABELLING LOOK LIKE?

The majority of packaged foods display a list of ingredients used in their manufacture on the pack. Where GM-derived ingredients which contain new DNA or protein are used in Safeway brand foods, they will be identified by an asterisk. A typical example of the new labelling format is shown below:

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Product example: "Safeway 2 Chicken Kiev's"

Ingredients:

Chicken, breadcrumbs, Butter Hydrogenated Vegetable Oil, Water, Wheat Flour, Lemon Juice, Salt, Soya Protein Isolate¹, Tarragon, Skimmed Milk Powder, Egg Albumen, Lemon Oil, Sodium Caseinate, White Pepper, Vegetable Oil, Garlic Extract

WHAT KINDS OF PRODUCTS WILL BE LABELLED?

Soya-based ingredients such as soya protein isolate are used in a variety of products from the Chicken Kiev example shown here, to sausage rolls. Such products will be labelled as outlined in this leaflet where the soya-based ingredient they contain is derived from genetically modified soya beans.

WHEN WILL THE NEW LABELS START TO APPEAR ON SAFEWAY BRAND PRODUCTS?

In January 1998 Safeway started to label products in accordance with voluntary guidelines and in advance of new legislation. Now that the legislation has been agreed, Safeway is working to ensure all appropriate products are labelled as soon as possible.

SHOULD I AVOID FOODS THAT ARE LABELLED AS CONTAINING GM INGREDIENTS?

By law all food offered for sale must be safe to eat. Genetically modified soya and maize have been approved by the appropriate regulatory authorities in both the UK and Europe. On this basis there is no reason for customers to avoid eating them or ingredients processed from them.

WHERE CAN I GET MORE INFORMATION?

We recognise that some customers may wish further information on genetic modification or ingredients processed from genetically modified crops. Further information on Safeway brand products can be obtained from Safeway Customer Services at the address below. Information on other brands can be obtained either directly from the manufacturer, or from the Food and Drink Federation. More general information on genetically modified foods can be obtained from the Institute of Grocery Distribution or MAFF at the addresses below.

Safeway Customer Services
Safeway Stores plc
Beddow Way
Aylesford
Kent ME20 7AT
Tel: 01622 712987

Communications Division
Food and Drink Federation
6 Catherine Street
London WC2B 5JJ

Institute of Grocery Distribution
Letchmore Heath
Watford WD2 8DQ

MAFF Helpline
Ministry of Agriculture, Fisheries and Food
Whitehall Place
London SW1A 2HH
Tel: 0645 335577

¹ Genetically modified.

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[Continued

Examination of Witnesses

DR ALASTAIR ROBERTSON, Technical Operations Director and MR TONY COMBES, Public Affairs Manager, Safeway Stores plc, called in and examined.

Chairman

223. Good morning, Dr Robertson and Mr Combes. Thank you very much indeed for coming to give evidence to our Committee on the subject of genetic modification in agriculture. I do not think there is any need for you to introduce your organisation, what we do not know about from our personal experience we have had the opportunity to read in the paper which you have kindly sent us. Perhaps you could just introduce yourselves individually and say what your responsibilities are.

(Dr Robertson) Good morning, Chairman. My name is Dr Alastair Robertson. I am the Director for Technical Operations for Safeway Stores. I will be your primary respondent this morning.

(Mr Combes) I am Tony Combes. I look after public affairs for Safeway's relationships with Government and also special interest groups like farmers.

224. We have taken evidence from Zeneca and we heard in that session about the tomato puree which you sell and they make. Could you say a bit more? Are there many other genetically modified products which you sell apart from that, perhaps you could say something about that? As far as the tomato puree itself is going, how is that comparing in its sales against the other brand?

(Dr Robertson) Genetically modified tomato puree is the only wholly genetically modified product that is currently in the market place. We launched that in 1996, February. We have other products in the market place now following the launch of GM soya which will contain soya and which are labelled to contain soya. As far as I am aware we and Sainsbury's have the only genetically whole product in the market place.

225. Are they rapidly increasing in number the products containing genetically modified soya which you label in that way?

(Dr Robertson) With the introduction of genetically modified soya then there will be a rapid increase in the number of GM products present in the market place. That will only be as an ingredient. As far as tomato puree is concerned, following the launch of that, we did that with full information on the pack advising customers that it was a genetically modified product. We had point of sale information which was very clear about the source of tomato puree. We had a help and advice leaflet and a help line that people could contact us on to talk about the product and understand it fully. We tried to define the benefits of that to the customers and then we had obviously the opportunity to provide an alternative product which was made from conventional tomato puree on the shelf by the side of it. So the customer was very much in charge of what they were shopping for. During that time we have now sold—Tony will correct me if I am wrong—in excess of 600,000 cans of the product and in fact in some of our stores it out-sells the

conventional product. We believe that provided customers have the whole information, total information and the choice then they will accept genetically modified products providing they have the benefits that they expect.

226. Are their sales fairly constant in comparison with each other or are they affected by some of the genetic scare stories?

(Dr Robertson) I think the answer to that is they have been climbing steadily since its introduction. We have seen no major issues in terms of volume sold during the so-called genetic issues which have arisen in the papers. In fact as a company we find we do not have many letters from our customers asking questions about, or criticising, the technology.

Lord Grantchester

227. Have you undertaken any research into consumers' attitudes generally?

(Dr Robertson) We undertook consumer research at the time of introducing the genetically modified tomato puree and subsequent to that we have done quite a lot of work with the Institute of Grocery Distribution undertaking consumer research as well. That was with respect to developing labelling guidelines that were produced through the Institute of Grocery Distribution.

(Mr Combes) Specifically on the puree, Zeneca did some research asking customers as they left stores what were their opinions of the tomato puree and the only complaint was that it was not available in a tube because this was in a tin. The benefit is it is 29 pence for 170 grammes which makes it 20 per cent cheaper which reflects the benefit that comes from growing genetically modified tomatoes, i.e. you do not have the 40 per cent wastage which you can get with conventional tomatoes when they are grown. So the consumer research came back that the customers were quite happy providing they were given a choice.

Chairman

228. That difference in price represents a real difference in cost to you, does it?

(Mr Combes) It is the saving that comes because the GM tomatoes are not wasted in the same way when the harvest is gathered in. You gather in conventional tomatoes, you put them in trucks to take from the fields to the factory and the tomatoes at the bottom of the truck get squashed by the ones at the top. That does not happen when the ripening process is carried on normally but the softening process has been delayed by a few days which is what happens.

Lord Jopling

229. But you tell us in your paper in paragraph two that you are charging for genetically modified tomato puree the same price. Does that mean you are profiteering out of it?

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DR ALASTAIR ROBERTSON and MR TONY COMBES

[Continued]

[Lord Jopling Contd]

(Mr Combes) No, it is the same price but it is 170 grammes whereas the conventional tomato puree in tins is 142 grammes.

230. I see.

(Mr Combes) So the customer recognises the saving and also some customers say that it tastes better but that is not a claim we have made.

Lord Wade of Chorlton

231. On this consumer issue, and public concern, obviously you have the places in your shops where people can go and complain about things and from what you are saying then how do any comments about these products compare with comments you have had on other products? Do you ever get any complaints about products, the consumer says: "This is not right. I do not want it. Take it out of your shop or I will not come here again" or that sort of thing? Does that happen with this product or does it not happen?

(Dr Robertson) I would like to say that we do not get complaints at all in our stores but clearly we do.

232. We have sat round this table and everybody gets complaints, we do so I am sure you do.

(Dr Robertson) We get complaints on a whole number of issues associated with our products, right the way down from quality to perceived safety issues. In terms of genetically modified puree we have had no more comments in terms of the safety of the product and certainly no comments regarding the quality.

Lord Rathcavan

233. Can I clarify one point, the cost to you of the GM tomato puree, is that 20 per cent less? You are selling it 20 per cent less, there is 20 per cent saving to the person who buys it but does it cost you a great deal less? Does the saving come through in your purchase price?

(Dr Robertson) Absolutely.

234. At the same level?

(Dr Robertson) Absolutely. I think the margins on the two products are virtually identical. It is a question one of my trading colleagues would be able to answer specifically but my understanding is that is the case.

Lord Redesdale

235. You were talking about experience so far with genetically modified tomatoes but there seems to be a growing movement and an awareness by consumers. Do you think that one of the reasons you have not had many complaints so far is that not many consumers realise that this is a genetically modified product in your tomato puree? I have a can here and it is not very clear labelling that it is a GM product. Do you think that with the consumer's concern growing you are going to get a lot more letters in the future and how will you deal with that?

(Dr Robertson) I do not believe we will regarding the tomato puree that you have just identified. I should say that, in addition to the on-pack information you

see there, we have at this time very large point of sale information which states the product is a genetically modified product and consumer leaflets as well. There is no mistaking that it is a genetically modified product. In fact, we had quite a lot of PR and media coverage at the same time as we launched it making sure that we were very upfront and clear to the consumer that these products were genetically modified. I have also taken part, with Tony in fact, in Scotland in one of our stores which outsells the conventional product of tomato puree, we have done some demonstrations of the product being used on pizzas and so on. We have shown the product, we have had them (consumers) taste the product on pizzas and we have asked the question are they concerned by the fact that the product is genetically modified? I think 90 per cent of the comments came back as being "it tastes better, therefore I am happy with it".

Lord Grantchester

236. What are the responsibilities of yourselves and retailers in relation to the responsibilities of companies developing genetically modified crops? Do you feel that these companies are discharging them? Have they been in close enough dialogue with yourselves as retailers and ready to work with retailers in your opinion?

(Dr Robertson) It is an important question and I think the answer to that is we have three rules in our business about selling products: firstly, they must be beneficial to our customer; we must provide the information and we must provide a choice. We did all those three things with Zeneca when we launched the genetically modified tomato puree. The same cannot be said when genetically modified soya entered the market place. It seems to me that companies who are producing genetically modified products need to realise that they are part of a food chain and they are not just ancillary to it. They need to understand that there are consumer issues at stake here and they need to understand what those are rather than considering that they only have one customer which may be, in their case, the primary producer or the farmer. We would say that companies that are now involved with genetically modified products must work quite closely with us. I think we are probably as close to the customer in the market place as anybody can be in the food chain. If we are going to be bringing these things to the market place we need to be able to do so at a rate which is acceptable to the consumer and their understanding. I think that all of us have a job to play in making sure that education and understanding is in place as we bring these products to bear. The problem we had with soya was one of two years ago, having one product on the shelf which actually was a genetically modified product or contained genetically modified ingredients, to currently the possibility of soya entering the food chain and being an ingredient of 60 per cent of the processed products that we sell. That is a huge change in volume and acceptance by consumers who do not fully understand the technology. In fact, you could argue that many scientists do not understand the technology either

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DR ALASTAIR ROBERTSON and MR TONY COMBES

[Continued]

[Lord Grantchester *Contd*]

unless they are directly involved with it. What we want to do as retailers is work with those companies to bring products into the market place which satisfy the conditions that we lay down. In other words they must be of benefit; we must provide the information in order to provide the choice. We do not want to be seen here as being an advocate of genetically modified foods, we are not. We are an advocate of bringing quality foods to the market place and if genetic modification can help that process then we will bring it to the market place with full information allowing our consumers to make their own choices as to whether they accept or reject the product or the technology.

237. Are you working closer with the companies developing crops, for example that the objective of the genetic modification should be portrayed and described at the retail end as well, ie what the crop is being modified for should also appear and be expressed to the consumer?

(*Dr Robertson*) Yes. One has to understand who the recipient of the technology is going to be ultimately. In the case of the biotechnology companies they only actually see the user, who might be the farmer, as being the recipient of the technology, failing to understand that if the consumer does not want to accept that technology then there will be problems with the technology long-term in its acceptability.

Lord Jopling

238. Are you aware of the work which has been reported in the press as having been carried out in Switzerland with regard to the effect on lacewing insects of introducing genetically modified maize which deters the ravages of corn?

(*Dr Robertson*) I am aware of the issue, yes.

239. Are you then not concerned that there is a whole host of similar indirect effects which could come out in a much more dramatic way than maybe the effect on lacewing insects where some unforeseen situation could emerge which could give rise to very serious public concern? Do you insure yourselves against those sorts of risks? How bothered are you about them?

(*Dr Robertson*) I think as a retailer we do not have the specific scientific knowledge to fully understand or work through the risks. We look to the expert advisory bodies to do that on our behalf and the regulatory process to operate on our behalf. We believe in the regulatory process as it stands. We accept that there are experts there who can assess the risks of a new technology but maybe we have an issue with the technology being so new that we cannot anticipate everything that will happen going forward. We do believe strongly that we should have post release analysis undertaken both in the environmental area and there is some discussion at the moment about doing it in the public health area as well. We would support post release analysis in all of those areas to evolve the technology so that we recognise the issues as they arise and put them right as they arise. We have to accept that we are in a position here where we are dealing with science and technology which has enormous

power and enormous benefit but there can potentially be some disadvantages and we have to understand those too.

240. Do you insure yourselves against these sorts of risks?

(*Dr Robertson*) I do not see how we can totally insure ourselves against the risk, except to believe in the regulatory process that we have and to endorse that and participate in it wherever we can. We are involved currently in the sub-committee of the ACNFP in its evaluation of public health issues associated with long term exposure to genetically modified products. I think that is a right and proper thing to do. It is right and proper that in anything that we do in technology and science and, indeed, in conventional food production we should assess the risk going forward and continually evolve our processes.

Lord Willoughby de Broke

241. There are two advisory committees, ACRE and ACNFP, that deal with safety matters. How should the broader issues be addressed in your opinion?

(*Dr Robertson*) I think that I have confidence, as I have already said, in the way that those two committees approach their work. Their work, as you rightly say, is about safety and environmental impact respectively in the two committees. I think they should continue to do that work. I think however there are other issues surrounding a brand new technology, which has an awful lot of potential power, that need to be addressed; consumer issues that should be looked at. At the end of the day, this technology, if it is to be of benefit in the future, needs to have the total acceptance of the consumer. We cannot expect, I think, to put technologies into the market place which few people understand without addressing those concerns as part of that process. I think we all have a job to do within that. The Government might think about setting up another kind of group to address, specifically, consumer confidence issues.

242. You welcome more consumer representation either on these committees or separate committees?

(*Dr Robertson*) Absolutely, yes.

Lord Jopling

243. Can I turn to paragraph eight in your paper in which you draw attention to the way in which European regulatory processes are lagging behind that of the United States. You refer, and I quote, to "... the potential to cause problems for EU importers and US exporters." You do not enlarge upon that and I think it would be interesting if you would be kind enough to do so?

(*Dr Robertson*) I think probably the word 'lagging' was an inappropriate word. I think we have a *slower* process in Europe, or I perceive we have a slower process in Europe, than there is in the United States. In the United States you have got basically the FDA and the USDA who are looking at the regulatory process, probably more from a scientific and objective perspective than I believe we have in Europe. In

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[Continued

[Lord Jopling *Contd*]

Europe we have to satisfy all the Member States and that process actually takes a lot longer than the process within the United States. It seems in the United States people are prepared to accept the judgment of the USDA and the FDA between them, and that then goes right across the whole of the United States. In Europe we have got a different situation where we have the different Member States. We have, probably, a more political system and we are not just looking at the regulatory process from the perspective of objective science. We have vested interest within the various Member States coming to bear as well. That is very slow. What we have seen with genetically modified soya was that the regulatory process was rapid in the United States, and it was allowed to enter the market place. In Europe we had not yet addressed the issue and suddenly we found we had a conflict between a product which was mixed, unsegregated, allowed to come into Europe and held at the ports whilst people were trying to understand the regulatory process which had not yet addressed all of the issues. That was really the issue behind that statement.

Lord Rathcavan

244. Dr Robertson, in your written evidence paragraph 10 you write of "Recent indecision and protracted debate over regulation is likely to have a lasting adverse impact on the future acceptance and market uptake of genetically modified crops." I wonder if you would like to expand on this?

(Dr Robertson) I think that just builds on my previous answer. In Europe we were waiting for the Novel Foods Regulation to come into being but knowing fully we had to deal with the introduction of genetically modified tomato puree on the shelf; knowing fully that we would have products following very closely behind and yet we had not addressed the issues in the Novel Foods Regulation. When the Novel Foods Regulation was enacted we still had not addressed the issues of how to label. Within this country we produced, through the IGD, the labelling guidelines for the industry. In fact it is interesting to note that only on May 31 (this year), I think, the labelling provision of the Novel Food Regulation was published and in fact it mirrors the principles of that which we wrote three years ago as an industry and we have worked to ever since. In fact, from January this year we started to label our products because we could not wait any longer. Public opinion was building to such a point that we had to do something and in the absence of any guidance from Europe we chose to implement those guidelines that we had laid down three years ago. Fortunately, the European guidelines, now that they have been published, mirror those exactly otherwise we might have found ourselves in a position where we might have had to change labels once again.

245. On acceptance and market uptake you told us earlier that there has been, good acceptance of the tomato puree in your view. Have you got plans for another pure genetically modified product like tomato puree? For example, as I understand it the Bt maize

has been approved, will you be deliberating marketing a GM cornflake, for example, in the future or do you again get to test public acceptance?

(Dr Robertson) I think the answer to that is no at this moment in time. Firstly, I think the Bt maize is not of the same variety as one would use in cornflakes; it is not available to us to produce that. If we did, we would look at it from the perspective again of the quality of the product, of the advantages that we could deliver to the consumer. At this stage I think what we are interested in doing is making sure that we have got the commodity products managed into the market place, customer acceptance of those, and then we will look forward and see what is available to us. At this moment in time most of the energy of the biotechnology companies is in looking at the commodity products because that is where the volume is and that is where the return on their investment is. The return on the investment on products such as tomato puree is remarkably low.

Lord Wade of Chorlton

246. In your paper you strongly support the concept of some post release monitoring. I would be interested to know how you would monitor it and by whom and what you would monitor for?

(Dr Robertson) As I said earlier when I was discussing post market release, I believe that it is important that the data one collects can be acted upon. I think in the area of environmental release the data one can collect is fairly robust, one can see what is going on in a relatively short period of time and one can develop the technology with respect to the information that one gains, the knowledge that one gains. I think what is already happening on environmental impact monitoring is a very good start. There is now a move to look at public health through the consumption of such products and that is much more tricky because I think long term public health is a multi-factorial issue. It is going to be very difficult to relate the data that one can collect of people consuming genetically modified products to long term public health several years down the road. I am cautious of that approach because I think if the data is not robust, if the statistical relationships are poor, then one could end up with creating scares where really there are not any scares. It is other factors creating those problems.

247. May I ask who do you think ought to pay for such a monitoring service? Is it something for the food industry or the retailers or the consumers or is it the Government's responsibility?

(Dr Robertson) It may be a bit of everybody's actually, except I would say the retailers. I think the issue is that in terms of the process which you set up, Government has a responsibility because Government allows these products I believe into the market place. It is their decision, we do not create that decision, we have to work with the material that we are given in the market place. It (post-harvest monitoring) is like every other surveillance programme Government carries out, it is a public health programme and an environmental

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[Continued]

[Lord Wade of Chorlton *Contd*]

health programme to ensure that both health and the environment are looked after. We have a responsibility I think in taking the long-term advantages out of genetically modified products, biotechnology as a technology, but making sure that we do not create any unanticipated issues in the near future.

248. It was not Government who said you had to stop this product, this was a decision that you made because, on the one hand, you said that business industry created the opportunity and science but, on the other hand, independent people had convinced you it was safe and the consumer wanted it.

(*Dr Robertson*) I think there is a very significant difference between the product that we put into the market place and the current products, which are commodity products. We worked very closely with Zeneca to introduce that (tomato puree) into the market place but we did so in such a way that we had limited market trials, limited growth areas, segregated products and we knew that if there was any issue there, then we were in a position to be able to trace it, take it back, recall it, take it out of the system. We made the decision to launch that product on the basis of those requirements. Zeneca clearly worked with us to achieve that. We have a significant difference now where we are putting in commodity products and mixing them with the conventional products. We are talking about large volumes getting into products; we cannot trace where they are and where they come from. I think the biotechnology companies have the responsibility to make sure that processes similarly robust and tight are in place.

249. Would it be fair to ask you what you think of Iceland's view on these matters?

(*Dr Robertson*) This is a Public Affairs matter.

(*Mr Combes*) Iceland has said publicly that they have no problems with the technology, they do not like the way it is introduced, talking about commodity crops. We would agree with them 100 per cent on that. Therefore, you wonder why they have taken full page advertisements in the national press questioning the safety of the product. I have said it in public, their Chairman is a member of Greenpeace and they have 1.6 per cent market share and they have 200 products which are affected by the soya. Therefore it is relatively easy for them to say "Right we are not going to have any GM soya in any of our own label products". They have said also it is unsustainable, I think that is the important part of that announcement, therefore there is an element of marketing in it.

Lord Gisborough

250. Do you think segregation is desirable and practical for all crops? What is the Government role? How are you getting on with your talks with the US agriculture agribusiness to encourage them to take the importance of segregation seriously?

(*Dr Robertson*) I do think that segregation is important, at least in the early stages of release into the market place. As I said earlier, when I was referring to the tomato puree, that is exactly what we did with that, we had limited growing areas within the United States

and the whole process was segregated and traceable right back from the product to the field. I think one of the problems that we have had with soya is that we have been unable to manage the product into the market place. We are not concerned about its safety, as I said earlier we believe in the regulatory process to deal with those issues, but we are concerned about being roller-coasted into having to introduce genetically modified products which we cannot trace back through our processes from field to fork. Over 50 per cent of our products now are own-brand and we spend a lot of our time as retailers with our technical teams, ensuring that we have got traceability of raw ingredients right the way through the process. We find in these situations (with GM commodity products) we cannot manage that, and the reason we cannot manage that is because we have not got segregated processes. It is important when we are releasing products into the market place that we should do so, at least for a short period of time, maybe one to two years, in a segregated environment.

Lord Grantchester

251. Can I come in with an auxiliary question on paragraph three where you state Safeway's position on genetic modification saying you are happy to sell food containing genetically modified ingredients provided it has gone through the regulatory process, etc.

(*Dr Robertson*) Yes.

252. Can I draw your attention to the last sentence in which you say: "In this respect Safeway is absolutely clear, and can state that it has no plans to sell genetically modified foods containing genes of animal or human origin." Can I ask you why it has no plans to sell and do you mean you are against it? Are you distinguishing genetically modified animals as distinct from genetically modified plants or are you saying that the transfer of genes from animals to plants is something that you might be against?

(*Dr Robertson*) Our position on it is that there really is no market place; we anticipate that there is no market place at this stage. We are discussing around this table the current issues that have resulted from genetically modified plant materials with plant genes. I think that at this stage in the game to introduce anything which has an animal gene associated with it would be unacceptable to our customers. However, that is not to say that situation will continue forever.

Chairman] Before we go down that line any further can we complete the subject of segregation which we were previously discussing.

Lord Gisborough

253. Do you think it is practical to have total segregation?

(*Dr Robertson*) I think it is practical, yes. I think it is practical as a third part of introducing a product into the market place. The first part of it is obviously the R&D trials and the information that needs to be generated to provide the ACNFP with sufficient information to make risk judgments. I think the second

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[Continued]

[Lord Gisborough *Contd*]

part of it should be a limited trial which allows it to go into the market place over a short period of time. Segregation over that period of time should be part of the regulations. I think the question I was asked earlier was "what role does Government play in it?" I think we are dealing here with a worldwide technology and I think we have to have worldwide regulation on this technology. It is not just about having a regulation in the United Kingdom or even within Europe when, in fact, world trade allows a different set of regulations and rules to bring these products into the market place. I think we should have segregation, it should be part of the regulatory process for introducing the product into the market place and it should be worldwide.

Chairman] Can we proceed to the question of labelling. Lord Moran, you have a question.

Lord Moran

254. Dr Robertson, you covered the question of labelling in very full and helpful detail in paragraph seven of your paper. We have seen Appendix 3, the draft advice to customers, which is very helpful. I suppose what you say means that you do think it is practicable for labelling to indicate whether GM processes have been used. I wonder if you could tell us what you think of the recent labelling agreement in Brussels and whether you think that is satisfactory and goes far enough or not? I wonder whether you could tell us anything about the relevance of thresholds and tolerances?

(*Dr Robertson*) Can I just pick up an issue on the question? We are in favour of labelling where genetically modified ingredients have been used but your question raised genetically modified processes and I think there is a substantial difference between those two things. We can label where ingredients are present and we would do that and agree with that.

255. Including the soya ones?

(*Dr Robertson*) Yes, including the soya ones. Where a GM process might be used, in other words where an enzyme is used as a processing aid, I think if we were to start moving into that area we would label every product that is available in the market place as genetically modified or having a genetically modified process. That would defeat the object of informative labelling, people would not wish to eat anything. Can you remind me of the last part of your question?

256. Brussels is the next one, the agreement, whether you think the agreement is satisfactory?

(*Dr Robertson*) The agreement has been long in coming so that was my original point. Now it is here I am satisfied with the labelling provisions in that I believe they quite closely mirror what we have laid down already (IGD voluntary guidelines) and that is to the benefit of the consumer, not to our benefit I should hasten to add. There are two issues then I think you raised, what should not be labelled and to what thresholds will people accept genetically modified or free from genetically modified materials? I think that is very important because of the sensitivity of the analytical methodology to have some threshold cut-off

that is acceptable both to consumers and industry. It needs to be low enough to be acceptable to consumers but high enough to be practicable to the industry to manage. We have to accept that there are going to be cross pollination issues which will create contamination. When we are getting into derivatives of soya, such as the oils and so on, or soya protein isolates, we are talking about cross contamination of the processes the beans are going through which will be legitimate. We have to set a level that is low enough to be acceptable to the consumer and high enough to be practical to the industry but not to endorse adulteration.

Chairman

257. Are you confident that the Commission will judge it correctly?

(*Dr Robertson*) The Commission are currently looking at that. Clearly we would like to have an input into those discussions, and I believe we probably will have the opportunity, through MAFF, to do.

Chairman] Lord Gallacher, you were going to ask a question on animal genes but I think Lord Grantchester has to some extent asked the question. I do not know if you would like to add anything.

Lord Gallacher] I think Dr Robertson has in answer to a supplementary dealt with the question of foods containing genes of animal origin and in the light of that I do not propose to ask it again.

Chairman

258. Does that mean you would not use the acid freeze gene taken from fish, for example, if that appeared in any product?

(*Dr Robertson*) What we are dealing with here is an evolving technology and we are also dealing with consumer perception of that technology. Scientifically we are talking about a DNA code which can have an impact within another species. That is not necessarily turning a tomato into a fish, it is expressing a particular chemical within it. If consumers accepted that technology and accepted the cross species issues associated with gene transfer then possibly in the future we may test the market place to see whether that would sell. Again we would apply the same rules: we would make sure that there was a benefit to the consumer, we would give them clear information about what we were doing, we would put the product on the shelf and we would have an alternative product by its side. If the consumer then chose not to accept that product then, like any other product we sell, it would come off the shelf. The answer is we do not, at this moment in time, deem it appropriate to put those sorts of products into the market place. In the future we would not like to make a comment, we would play it as the technology advances.

259. The answer is you might?

(*Dr Robertson*) Yes.

260. I had a question on industrial crops which you made a reference to in your paper at paragraph

17 June 1998]

DR ALASTAIR ROBERTSON and MR TONY COMBES

[Continued]

[Chairman Contd]

four. You said these could have benefits for the environment. Can you expand on that a bit?

(Dr Robertson) The comment was really regarding the fact that we produce quite a number of crops or we use crops to produce things like modified starches, particular oils, for particular purposes. That process requires the growing of crops, it requires the processing, the isolation, the purification of those materials and then the process of making modified starches for example. If crops could be produced with that end purpose in mind, so it was easier to extract, for instance, starch out of potatoes or to undertake the modification process, then clearly there would be benefits in terms of energy savings, just general environmental savings. The intention of using genetic modification for subsequent industrial processes is a potentially viable and beneficial thing to do in terms of the impact on the environment.

261. Does that apply also to the genetically modified food crops?

(Dr Robertson) Yes, it does, and in fact the benefits we conveyed to our customers, as Tony said, were that there was less wastage of the product, the product had a much higher dry matter content so it required much less in the way of energy to remove the water from it and basically the whole process was much more efficient and effective. So we had environmental savings in that way; less water used in the growing of the crop being another.

Lord Rathcavan

262. Dr Robertson, are you concerned that in the future there could be a material level of imports from third countries, such as China, without any means of telling whether they are GM foods or not? What might be done about this or does your field to fork policy override your own involvement? Really the question is not just for yourselves but for the general market place and the potential problem.

(Dr Robertson) I think there is a major concern that if there is not some form of global regulation of the process and global monitoring of the process one could have third countries, particularly China is a good example, where the technology is available to them but we have no way of understanding or managing that process in terms of food products that may enter our market place. This is a particular issue when it comes to commodity products. China is not yet entering the world market place in terms of its crop production but could do in the future and could provide really severe problems for us. This brings me back to a comment I made earlier that regulation is a global requirement, monitoring is a global requirement, and I think that is an important role for Government to play.

Chairman] On that note can I thank you both, Dr Robertson and Mr Combes, very much indeed for having come along today to help us. It has been very useful and interesting evidence. Thank you.

WEDNESDAY 24 JUNE 1998

Present:

Gallacher, L.

Gisborough, L.

Grantchester, L.

Jopling, L.

Moran, L.

Rathcavan, L.

Reay, L. (Chairman)

Redesdale, L.

Willoughby de Broke, L.

Young of Old Scone, B.

Clanwilliam, E.

Memorandum by the National Farmers Union of England and Wales

The NFU welcomes the opportunity to comment on this topic and would respond as follows:

1. INTRODUCTION

The NFU, in concert with COPA/COGECA, welcomes the introduction of emerging biotechnological innovation into farming. It can provide clear advantages, although, as with any other new technology, there are also recognised risks that have to be addressed. As a recent COPA/COGECA document states, "authorization of placing GMOs on the European Union market must be based on comprehensive assessment of experimental data over a sufficiently long period so as to provide the general public with maximum security for human and animal health as well as environmental protection". A copy of this document is appended (Appendix 1). It should also be mentioned that this approach is similar to that of the European Parliament Committee on Agriculture and Rural Development as stated in the report on the impact of biotechnology on agriculture (Appendix 2) [*not printed*]. A similar approach has been developed by the NFU as is outlined in the appended Report of the Biotechnology Working Group, March 1998 (Appendix 3).

2. THE PRESENT UK REGULATORY SYSTEM

The two regulatory bodies that are involved in biotechnology topics as they relate to farming in the UK are the Advisory Committee on Releases into the Environment (ACRE), and the Advisory Committee on Novel Foods and Processes (ACNFP). One of the possible difficulties with these two committees is that they have different departmental loyalties. ACRE have the responsibility of "advising the Secretary of State on human health and environmental safety concerning the release of GMOs into the environment". It is serviced by the Department of the Environment, Transport and the Regions. The remit of the ACNFP is to "advise Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Social Services and Agriculture for Northern Ireland on any matters relating to the irradiation of food or to the manufacture of novel foods or foods produced by novel processes having regard where appropriate to the views of relevant expert bodies". It is serviced by the Department of Health and the Ministry of Agriculture, Fisheries and Food.

3. CHANGES TO THE REGULATORY SYSTEM PROPOSED BY THE WHITE PAPER ON THE FOOD STANDARDS AGENCY

While we understand that there has been informal contact between ACRE and the ACNFP we welcome the proposal in the white paper on the Food Standards Agency that the responsibility for both ACRE and the ACNFP are to be subsumed by this new agency on its formation. This should lead to a more integrated approach to the regulation of genetically modified organisms (GMOs) and their use in agriculture and food.

The NFU also welcomes the acceptance of the recommendation of the Lamming Committee for the creation of an independent Advisory Committee on Animal Feedingstuffs. No doubt this committee will have to take account of the need to properly label animal feedstuffs that will increasingly contain genetically modified constituents. The proposed changes to amend EC Directive 79/373 and repeal Directive 82/471, which relates to the specific raw materials in animal feedstuffs, should be relevant to the activities of this new committee. The new Directive contains sections that are concerned with the requirements to ensure that animal feedstuffs are appropriately labelled, including information on constituents derived from GMOs.

An unexpected recommendation included in the white paper was that animal biotechnology will continue to be under the purview of the Department of Agriculture. While there may turn out to be aspects of this subject that are not appropriately covered by ACRE or the ACNFP, or their successors, there will appear to be a need for consultative processes to be established when the Food Standards Agency has been put in place.

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[Continued

4. A SUGGESTED OVER-ARCHING COMMITTEE

One of the criticisms of the present UK regulatory structure that always arises when non-governmental organisations, the NFU and industry representatives come together to discuss biotechnology is the lack of an over-arching body. Such a body would be expected to discuss more global issues, such as is it advisable for UK agriculture to go the route of using herbicide tolerant or pesticide-containing genetically modified crops? The inclusion of ACRE and the ACNFP in the Food Standards Agency would present the ideal opportunity for such an over-arching committee to be established.

5. PROPOSED CHANGES TO THE REGULATORY PROTOCOLS

In general the NFU considers that the present UK system has worked well. However, there have been some difficulties presented by the system and some additional procedures would be sensible prior to commercial growing of GM crops in the UK.

(a) *Post-release monitoring*

The NFU is concerned that there is currently no requirement for monitoring possible environmental changes after consent to market has been granted. We recognise that widespread monitoring could be difficult and costly and that a condition of the consent to market a GMO requires the applicant to inform the Secretary of State of any environmental problems that subsequently occur. Nevertheless the NFU has proposed that a post-release monitoring programme be instituted. The monitoring programme should be independent of the company that is expected to profit from the GMO, should be paid for by government, and should be directed by government, or under government contract. The post-release monitoring programme should extend over a period of, say, 10 years and the review that derives from it should form the basis for the continued licensing of the GM crop. The report and data that arise from the monitoring programme should be in the public domain. Any major environmental changes that arise within the monitoring period could lead to immediate withdrawal of approval. Prompt action would then have to be taken to limit environmental damage if such an event occurred.

The NFU welcomes the suggested changes to EC Directive 90/220 on deliberate release of genetically modified organisms to the environment which include a provision for a mandatory monitoring of products after they have been placed on the market linked to a consent granted for a fixed time period of seven years.

(b) *Antibiotic-resistant marker genes*

One of the first genetically modified crops that was adopted for commercial planting was Novartis's (formerly Ciba-Giegy's) *Bt* maize. This contains an antibiotic-resistant "marker" gene. The ACNFP recommended against the authorisation of this product for growing in the UK and Europe because of the perceived risk of the marker gene being transferred to the bacterial inhabitants of the gut of livestock fed with feedstuffs that included it, and the eventual possibility of the antibiotic resistance being passed on to human pathogens. This risk was considered to be low but it was felt that further investigations were warranted before the use of the maize was authorised. This recommendation was eventually overturned by an EC majority vote, which led to considerable public protest in various parts of the EU. The whole matter is not yet resolved as various legal and technical challenges to the decision have not yet been concluded. For example, Austria is still refusing to accept the maize. It is ironic that the level of risk is presently being investigated via several MAFF research contracts. It would have been prudent for the EU to have insisted on such investigations *before* growing authorisation was granted. In the event the *Bt* GM maize is being commercially grown in the EU for the first time this year. It is estimated that between 1,000–2,000 hectares are being grown in France, and some 15,000 hectares in northern Spain.

A precautionary principle should be the basis for all EU decisions of this sort. If there is any doubt as to the safety of a product it should *not* be authorised for use in the EU unless the level of risk has been determined through properly targeted scientific and technical research. The two terms are used advisedly, as knowledge of the likelihood of gene transfer between maize in feedstuff and gut bacteria requires scientific investigation, but information is also needed as to whether the DNA of concern is properly inactivated by the maize processing regimes, which in essence is a technical problem.

(c) *Test site information provision*

The upsurge in eco-terrorist actions has brought into sharp relief the difficulties posed by the UK regulatory system that makes available full information of the location of a GM crop test site before growing is undertaken. There is clearly a "right to know" issue here as far as the general public are concerned. However, giving potential eco-terrorists detailed information that will allow them to unlawfully destroy test sites hardly seems helpful and should be reviewed.

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[Continued

6. CODES OF PRACTICE

One way of assisting farmers and growers, and other members of the agri-food chain, to deal with the introduction of GM crops is to develop appropriate codes of practice for growing them. Two have so far been produced and were introduced in April 1997. The first was the joint BSPB/NFU/UKASTA Code of Practice on the provision of information relating to genetically modified crops, and the second was the NFU Code of Practice to establish a consistent approach to providing information to farmers and growers regarding genetically modified crops. In addition there was a joint response to the MAFF consultation on genetically modified herbicide tolerant crops produced by the BAA, BSBSPA, BSPB, NFU and UKASTA (these three documents are provided as Appendix 4).

One feature of the codes is the requirement for a clear identifier that a seed is genetically modified to be placed on all seed packets/sacks. This should be supplemented by more detailed information, which should be supplied in a leaflet that accompanies the seed, sales literature and the NIAB recommended lists. The explanatory information should provide details of the specific genetic modification, and should give details of the agronomy of the GM plant. Farmer training schemes may also be necessary. When the crop is harvested the produce should be identity preserved so that the GM crop can be segregated from the non-GM crop if it is deemed to be necessary. Each GM crop consignment should be accompanied by a post-harvest declaration, which should also include the name of the variety. The provision of such information should be maintained during subsequent transportation. These codes of practice will require detailed record keeping both on and off farm, which form the basis of traceability of the crop.

As a result of these activities a group has been formalised to extend such initiatives. It is the Supply Chain Initiative for Modified Agricultural Crops (SCIMAC). At present its members are in the process of completing a set of guidelines for growing herbicide tolerant crops. The intent of all these actions is to ensure that the commercial growing of GM crops in to the UK is carried out in a responsible manner.

7. LABELLING

The situation with labelling brings into sharp relief the chaos that has undermined the credibility of the EU regulatory actions with regard to the introduction of GMOs. The hard won EC Directive on Novel Foods and Novel Food Ingredients (Regulation No. 258/97), which was intended to harmonise regulatory controls in Europe, came into force in May 1997. It was expected to calm consumers' concerns about GMOs. Unfortunately it did not do so. The problem was that the regulation did not cover GM products that had previously been approved or ones that were presently being considered. Some consumers have also been concerned that a food was only considered to be a "novel" one, and so covered by the legislation, if it was "*no longer equivalent*" to an existing one. In addition, while a particular food may not be covered by the novel food regulations, there can be consumer concerns about how a particular product had been produced (an example of this could be sugar that had been produced from GM herbicide tolerant sugar beet).

The problem was that genetically modified soya and maize, grown in the USA or Canada (and now in other countries) was being imported into the UK and Europe in increasing amounts. It was not segregated so that the separation of GM soya or maize from non-GM soya or maize was not possible. The products of either crop were not considered to be covered by the novel food regulations so that no special labelling was required. Extensive public unease about this situation caused a re-think in this attitude. A decision was made to produce an EC regulation that covered the labelling of products that contained derivatives of GM soya and maize. This is EC Regulation No. 1813/97 that directed that "genetically modified soya beans covered by decision 96/281/E", and "genetically modified maize covered by decision 97/98/E" should now be covered by the Novel Food Regulation, and should consequently be labelled. However, this regulation is still not in place, although agreement on the components of it has now been reached. For example, a third category of labelling of "may contain GM material" has been removed. Also, labelling will only be required if a product contains novel protein or DNA. A list of products that do not need to be labelled is to be produced.

In the meantime, the Institute of Grocery Distribution, of which the NFU is a member, instituted voluntary labelling guidelines in November 1997 for products that contained soya. The basis of these guidelines was that *any* food that contained soya probably contained at least a very small amount of GM soya, so that all such products should be labelled as "containing" GM soya. This labelling initiative has also been supported by the Business Retailing Consortium and the Food and Drink Federation. The voluntary guidelines have now been extended to include foods containing maize. Labelling of on-shelf foods under this scheme started in early 1998 and should be completed by the end of the year.

It is clear that, commendable as it might be, the voluntary labelling scheme would never have been necessary if the EU had dealt with the problem with speed and precision at the outset. One of the major difficulties with the EC is that it has to balance the conflicting requirements of its member countries. This often means that decisions can be very slow in coming, and that when they do occur the regulations are not always sufficiently detailed to deal with the problem at hand.

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[Continued

8. EC DIRECTIVE FOR THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Following many years of negotiations, and the failure of the 1995 draft EC Directive because of ethical objections, a revised version has recently been accepted by the European Parliament. It should be noted that the NFU has been one of the groups instrumental in ensuring that clauses were included in the revised version of the Directive that should protect farmers' rights with regard to GM crops and livestock. These rights would include the right to "use the product of his harvest for the reproduction or propagation by him on his own farm", and "implies authorization for the farmer to use protected livestock for an agricultural purpose. This includes the sale for the purpose of agricultural activities". The NFU welcomes the new Directive as it is felt that it will harmonise regulations in the EU and will produce a legislative atmosphere that should encourage innovation in the biotechnology area in Europe. However, it should be pointed out the Directive is thought to be likely to come into force in September 2001, two years after completion of the necessary ratification procedures in the member states. Such a lengthy delay points out the limitations of the EU regulatory system in comparison with those of a nation state such as the UK.

9. INTERNATIONAL HARMONISATION

The NFU is concerned that products of genetic modification are reaching the market in Europe before harmonised controls are in place. We believe that international guidelines for safety assessment are crucial and support programmes being developed in this area by the United Nations Environmental Programme, the World Health Organisation, the United Nations Food and Agriculture Organisation, the Organisation for Economic Co-operation and Development, and Codex Alimentarius.

The NFU is aware of the concerns of underdeveloped and developing countries on the possible exploitation by multinational companies of products derived from their naturally occurring flora and fauna. The NFU supports attempts to develop international agreements in this area.

10. INFORMATION

One of the failings of the UK and EU regulatory climate is the lack of accurate information that has been provided to the general public. Individual bodies such as the NFU, IGD, FDF, and individual supermarkets have provided some information. However, with some notable exceptions, such as the BBSRC, government sources have not done so. It is the opinion of the NFU that a government funded information strategy should be devised so that the benefits and possible risks of the introduction of biotechnology into farming could be presented in a balanced manner from a source that is (hopefully) regarded as neutral. This would aid in countering the distorted information on biotechnology that is often presented by non-governmental organisations that are opposed to the technology.

Acronyms

ACNFP—Advisory Committee on Novel Foods and Processes

ACRE—Advisory Committee on Releases into the Environment

BAA—British Agrochemicals Association

BSBSPA—British Sugar Beet Seed Producers Association

BBSRC—Biotechnology and Biological Sciences Research Council

BSPB—British Society of Plant Breeders

BT—*Bacillus thuringiensis* (a soil bacterium that is a natural source of pesticides)

COGECA—Comité Général de la Coopération Agricole de l'UE

COPA—Comité des Organisations Professionnelles Agricoles de l'UE

FDF—Food and Drink Foundation

GM—Genetically modified

GMOs—Genetically modified organisms

IGD—Institute of Grocery Distribution

MAFF—Ministry of Agriculture, Fisheries and Food

NFU—National Farmers' Union of England and Wales

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[Continued

NIAB—National Institute of Agricultural Botany

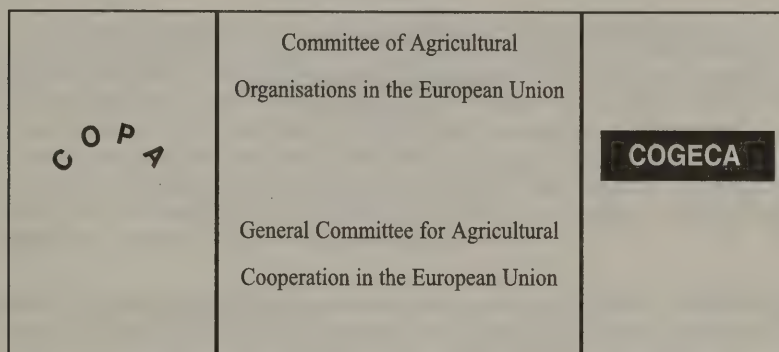
SCIMAC—Supply Chain Initiative for Modified Agricultural Crops

UKASTA—United Kingdom Agricultural Supply Trade Association

10 June 1998

APPENDIX 1

AGRI INFO—COPA COGECA—Crops: Miguel GARCIA NAVARRO; Source: COPA COGECA;
Date sent 22-4-1998



Comité des Organisations Professionnelles Agricoles de l'UE w Comité Général de
la Coopération Agricole de l'UE

INITIAL POSITION ON BIOTECHNOLOGY AND THE USE OF GENETICALLY MODIFIED
ORGANISMS (GMOS) IN AGRICULTURE WITHIN THE EU INITIAL POSITION ON BIOTECHNOLOGY
AND THE USE OF GENETICALLY MODIFIED ORGANISMS (GMOS) IN AGRICULTURE¹
WITHIN THE EU

New techniques acquired through biotechnology which allow for production of genetically modified organisms (GMOs) are undergoing rapid development on a worldwide scale. Farmers and their co-operatives wish to open a constructive dialogue on this subject with consumers and all other relevant parties. They would in particular wish to discuss the implications of the use of GMOs as regards health, ethic, environmental protection, methods of agricultural production and commercial, economic and political aspects. COPA and COGECA have to this end approved the principles outlined below which will be taken into account when taking a position on future developments in the field of biotechnology. COPA and COGECA request that a procedure for consulting farmers and their co-operatives be set up.

1. The European Union cannot isolate itself politically, economically and commercially from the developments in the field of biotechnology. It must consequently reinforce its policy in terms of research and development as well as authorisation and post-release monitoring in order to remain at the forefront of these developments.

2. The use of GMOs can present advantages for society, but it can also pose risks. Ensuring transparency and the supply of correct and complete information for all those working in the sector from farmers to consumers by means of an appropriate labelling system which may be monitored are indispensable if they are to make well-informed decisions. To this end, a global authorisation, labelling and control system is required both for Community products and imported products so as to ensure that any problems which may arise are identified and resolved.

3. To ensure safety and the confidence of consumers as well as farmers, the European Union must set up an independent scientific body responsible for the following matters relating to GMOs:

- the application of a transparent and reliable procedure for assessment of all possible risks, for authorising placing on the EU market and for monitoring after release;
- contributing to the development of an international reference framework.

4. For COPA and COGECA, authorisation of placing GMOs on the European Union market must be based on the comprehensive scientific assessment of experimental data over a sufficiently long period so as to provide

¹ This position has been based primarily on the present situation within the arable sector.

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[Continued

the general public with maximum security for human and animal health as well as environmental protection. Authorisation may be granted only on condition that constant post-release monitoring is carried out, in particular, with regard to health and environmental protection. Such an assessment procedure must also make it possible to ensure that products authorised in other regions of the world present the same guarantees.

5. The production, marketing, processing and import of GMOs may only be authorised within the European Union in accordance with the Community procedure outlined above. The current risk of distortions of competition which has emerged as a result of the recent authorisation of marketing and processing GMOs from the United States within the European Union is unacceptable and must be avoided in future.

APPENDIX 3

REPORT OF THE BIOTECHNOLOGY WORKING GROUP

*Presented to NFU Council
March 1998*

EXECUTIVE SUMMARY

INTRODUCTION

The potential benefits of the application of biotechnology to UK agriculture and horticulture are outlined. Some concerns about the technology are given, and suggestions for future action are made.

BENEFITS

Biotechnology provides additional opportunities to adapt to the pressure for change. It cannot solve all our problems, but can play an important and innovative role in maintaining the competitiveness of UK agriculture and horticulture. Biotechnological innovations have the potential to make farming and growing more effective by maximising potential yields, improving the consistency, nutritional content and quality of crops, and by reducing pesticide and herbicide use. Other benefits relate to the development of perennial crops, crops that can fix nitrogen, and plants that are more resistant to disease, cold, drought, salinity, and higher temperatures. Manipulation of features of plants that control flowering, germination, photoperiodism, growth, and shade avoidance, should also give benefits.

Genetic modifications that are sensitive to local farming conditions may also provide a means of increasing the reliability of food production in underdeveloped and developing countries in response to an increasing world population. Bioremediation of polluted soils, and similar developments could also prove to be beneficial. It should be emphasised that the modifications required to obtain the benefits referred to in this paragraph would be very difficult, if not impossible, to achieve by conventional breeding methods.

In animals the use of genetic markers for breeding purposes is likely to improve animal welfare. This will be by breeding animals that are more resistant to disease and parasites, and have improved reproductive efficiency. Further potential benefits include parentage verification, and identification of traits for high feed conversion efficiency and improved carcass quality and meat purity. The use of transgenic animals for the production of pharmaceutical products and possibly as a source of organs for humans (xenotransplantation) are other benefits.

CONCERNS

The recognised risks of the introduction of biotechnology into farming are considered by most observers to be low. However, there are some concerns. The first relates to the use of antibiotic resistant marker genes in genetically modified crops. The likelihood of gene expression is determined by the type of DNA promoter sequence that is associated with the marker gene. It is possible that specific antibiotic resistance could be transferred to livestock and to humans. While this risk is considered to be very small the NFU has a policy that discourages the use of such genes. They are unacceptable to many consumers and alternative marker genes are available.

Other concerns are environmental and relate to the integrity of the food chain. For example, there is the possibility that resistance to a variety of herbicides could become transferred to and aggregated into a weed species so that it becomes difficult to control. There is also the possibility that the use of herbicide tolerant crops, and ones that contain a built-in pesticide, could reduce the number of insects so that predatory species, ranging from other insects to birds and mammals, may be reduced in numbers. Resistance to in-built pesticides

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[Continued

may also develop in insects, so reducing the availability of effective pesticides. Because of these environmental uncertainties the NFU recommends that a 10 year monitoring period be instituted when a specific genetically modified crop is commercially grown in the UK for the first time. The results of the monitoring programme should be in the public domain, and should form the basis for continued registration of the genetically modified crop.

Animal welfare concerns have centred on the rapid development of reproductive manipulation methods. For example, the excessive size of animals at birth produced by *in vitro* reproductive methods, including cloning, certainly has negative animal welfare implications. A further welfare concern with cloning is the risk related to the potential vertical transmission of disease from donor to cloned offspring and surrogate mother (e.g., bovine viral diarrhoea).

FOOD LABELLING

The NFU has a policy that genetically modified crops should be segregated when grown in the UK so that traceability and appropriate labelling is possible. However, experience gained in segregating the Canadian canola crop in 1996, and detailed consideration of the practicalities of such practices suggest that complete segregation is difficult to achieve and can be costly. Labelling would enable consumers to choose whether or not they wish to eat a food that contains material derived from genetically modified crops. Codes of practice, developed by the NFU, in association with the British Society of Plant Breeders and the United Kingdom Agricultural Supply Trade Association, aim to ensure that GM crops grown in the UK are segregated throughout the food chain so that they can be appropriately labelled to allow consumer choice.

IMPORTED GENETICALLY MODIFIED COMMODITY CROPS

The importation of unsegregated genetically modified crops such as soya and maize have provided UK consumers with little choice. While there is no simple answer to this problem, the Institute of Grocery Distribution, supported by the NFU and other groups, has produced voluntary labelling guidelines for foods derived from genetically modified constituents. These were introduced for genetically modified soya and maize in 1998. It is likely that all foods which contain such products will have to be labelled in the future. However, labelling is unlikely to be required for foods that do not contain the genetic material (DNA) in its native state (e.g., oils, sugar, etc.). Because of discrepancies between the United States and Europe it has become obvious that internationally agreed regulations to control the introduction of biotechnological innovations into farming are urgently required. The NFU fully supports attempts to harmonise regulations at European and international levels.

PATENTING

The NFU is sensitive to the concerns of undeveloped and developing countries on the possible exploitation by multinational companies of products derived from their naturally occurring flora and fauna. The NFU supports attempts to develop and harmonise international legislation in this area.

Following many years of negotiation a revised draft of the EC Directive for the Legal Protection of Biotechnological Inventions, which aims to harmonise intellectual property laws in the EU member states, appears likely to become law in the near future. The NFU has been one of the groups who have been instrumental in ensuring that clauses are included in the Directive that should protect farmer's right with regard to genetically modified crops and livestock. These rights would include the right to "use the product of his harvest for reproduction or propagation by him on his own farm", and "implies authorization of the farmer to use the protected livestock for an agricultural purpose. This includes the sale for the purposes of agricultural activities".

PROVISION OF INFORMATION

The NFU is committed to providing accurate up-to-date information on biotechnology and farm use. In addition practical instruction may also be required. The NFU also believes that information on biotechnology should be freely available to the public, and is encouraged by the variety and number of sources of information that are now available. These range from supermarket leaflets to detailed explanatory booklets. These should allow the public to develop their attitudes to biotechnology based on science rather than supposition.

CONCLUSION

The NFU is committed to the development of sound agriculture practices. The NFU believes that the responsible introduction of genetically modified crops and livestock will form part of this farming equation in the future.

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[Continued]

1. INTRODUCTION

This report examines the potential benefits of the application of biotechnology to British agriculture, horticulture and associated processing and manufacturing industries. It identifies a number of concerns and makes suggestions for future action.

2. WHAT IS BIOTECHNOLOGY?

In the broadest sense biotechnology is the use of biological processes in industry. Biotechnology plays a part in the making of cheese, bread, wine and beer which all utilise natural biological processes. However, the term "biotechnology" is now more commonly applied to modern technologies such as genetic modification, genetic fingerprinting and antibody technology.

Biotechnology covers such a broad spectrum of techniques and applications that it cannot be accepted or rejected as a whole. Different applications offer different opportunities and raise different concerns. This must be recognised and an assessment made case by case regarding benefits, risks and ethical concerns.

Within this document the term "biotechnology" is restricted to the range of techniques and applications that can be used in the production and manufacture of animal and crop based products. The science underlying biotechnology is advancing rapidly. We can therefore only examine the technology available today. No doubt future applications will offer further benefits and present different concerns.

3. JUSTIFICATION AND NEED

UK agriculture and horticulture are part of a food industry which is adapting to the pressures of change from an expanding European Union, CAP reform, GATT and environmental pressures, as well as responding to changing consumer concerns and market requirements. In order to survive and succeed UK farmers and growers must continue to be competitive primary suppliers to the food chain. They must continue to minimise costs, improve productivity, enhance quality and develop new market opportunities while maintaining high animal husbandry and welfare standards, and helping to protect the environment.

Biotechnology provides further opportunities to adapt to the pressures for change. It cannot be the solution to all our problems, but can play an important and innovative role in maintaining the competitiveness of UK agriculture and horticulture.

Biotechnology was identified as one of the most promising technologies for sustainable development in the Commission of European Communities' 1993 white paper "Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st century". It was also pinpointed as a key area for future development in the Governments' Office of Science and Technology document entitled "Progress through Partnership", which was the report from the Steering Group of the Technology Foresight Programme 1995. One of the key recommendations in that report was the need to "Exploit the growing capabilities of biotechnology to modify the properties of agricultural products." The UK has the strongest scientific and industrial base in the EU in biotechnology and so there is considerable scope for development in that area.

4. THE BENEFITS

The NFU believes that biotechnology may help improve the efficiency of production, develop new market opportunities, enhance the marketability of many existing products and contribute to better standards of animal health and welfare. We also believe biotechnology is capable of delivering environmental benefits.

4.1 *Efficiency of Production*

Biotechnology has the potential to improve the efficiency of production. Genetic mapping and marker-assisted breeding programmes are already being used to develop, through conventional breeding processes, livestock and crop varieties with improved performance. The development of biotechnological kits for rapid diagnosis of disease will allow more targeted disease and pest control. Genetically modified crop varieties which are resistant to pests or a specific herbicide are already in the marketplace. These can be used as part of integrated crop management systems and can reduce the need for pesticides and herbicides. Other developments that could lead to more efficient farming are the development of perennial crops that would be sown once and harvested each year. This would lead to a reduction in labour costs, and would have environmental benefits by reducing soil erosion and encouraging better water retention. Crops that were modified to include root nodules that could fix atmospheric nitrogen would greatly reduce the need for the application of nitrogen fertiliser.

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The use of these new technologies could result in fewer losses from disease, reduced expenditure on agrochemicals and veterinary medicines, and increased marketable yields.

4.2 *New Market Opportunities*

Biotechnology can be used to develop new crops and extend uses for existing crops offering wider market opportunities for the farmer and grower. For example, oilseed rape plants from which biodegradable plastics may be produced have been bred using genetic modification. These plants are now being further developed and may provide a cheaper and renewable source of plastic. The development of livestock that produce milk with reduced allergenic properties is another possibility. The development of crops that have a greater climatic range may allow the growing of plants in the UK that will produce products to supplant those presently imported.

Other potential market opportunities include biofuels from modified fast growing trees, new varieties of ornamental, industrial oils, cosmetics, paper production, pharmaceuticals and novel foods.

It is likely that this technology will initially be used to develop a range of niche markets for a small number of farmers and growers.

4.3 *Marketability of Existing Products*

Biotechnology can be used to modify food to meet consumer needs more closely. Market research indicates that better eating quality, reduced allergenic properties, improved flavour, enhanced safety, superior nutritional content, and environmental gain, are of increasing importance. In addition, food manufacturers and retailers are seeking ways to add value, differentiate their products, reduce waste and satisfy the ever-increasing demand for convenience foods.

The application of biotechnology has the potential to help meet these changing consumer needs—not least by offering a wider choice of better value for money products which are attractive and safe. Improvements can be made to fresh produce and to the raw materials used in the manufacture of processed foods. The introduction of more desirable food processing characteristics could mean less processing and less waste. Biotechnology can also be used to add value beyond the farm-gate, for example, through the use of food processing enzymes to enhance flavour. Through using this technology to meet consumer needs, benefits should accrue to primary producers, food processors and manufacturers and to the retail sector.

Plant and animal breeders as well as food processors and manufacturers are already striving to meet consumer needs using conventional methods. Biotechnology can help to achieve their objectives. Below are two examples:

Genetic modification in potatoes could:

- Increase availability of UK varieties by extending growing seasons through introducing stress tolerance characters.
- Improve flavour and mash texture through modification of starch and sugar content.
- Reduce the water content in potatoes to limit the fat retained in crisps and chips and meet the processors' needs more closely.
- Extend shelf life by suppressing sprouting and reducing rots.
- Reduce chemical residues by introducing herbicide tolerance, disease and pest resistance traits.

In pigs, biotechnology could:

- Help improve animal health through the development of new vaccines and diagnostic kits for rapid disease diagnosis.
- Give the potential to provide disease and parasite resistant animals and so improve animal welfare.
- Improve flavour, texture and fat content and distribution through the application of marker-assisted breeding technologies.
- Improve the efficiency of food surveillance through the development of rapid tests for bacterial contamination or antibiotic residues.
- Include opportunities for xenotransplantation.

4.4 *Animal Health and Welfare*

Biotechnology could make a major contribution to animal health through the development of new vaccines and diagnostic systems. Genetic mapping and marker-assisted breeding could also be used to help select for disease and parasite resistance characters.

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Vaccination is a central strategy for disease control. Genetic modification can be used to develop new, more effective vaccines. These could be particularly important for viral infections which have proved difficult to control through conventional vaccines. The use of such vaccines in human medicine is already well accepted.

Diagnostic systems based on antibodies will provide rapid and accurate disease diagnoses. Such systems are highly sensitive and will detect very low levels of a pathogen. They are likely to prove a valuable veterinary tool. While not only of welfare interest, diagnostic systems could be used to improve parental verification and provide other genetic information.

4.5 Environmental Benefits

Applications of biotechnology could help reduce our dependence on chemical inputs. For instance, in-built pest resistance and built-in herbicide tolerance, developed through genetic modification, are already being used with genetically modified maize and soya as part of integrated crop management systems in North America.

The use of biotechnologically produced diagnostic kits which are accurate, sensitive and reliable will allow more targeted pest control. Agrochemicals can then be applied only when and where needed, reducing the total amount used.

"Cleaner" raw materials for manufacturing could reduce the amount of harmful chemicals released into the environment. For example, the oil profiles of oilseed crops are being modified to provide industrial feedstocks such as adipic acid for nylon production and lauric acid for detergents. This resource is renewable and potentially more environmentally friendly (or "cleaner") than the conventional petrochemical feedstock.

Biotechnology is already used for cleaning up waste and contamination. Techniques used for bioremediation are likely to be further developed to allow cleaning up of soil contaminated with pesticides, heavy metals, or other pollutants. This could help "repair" environmental damage.

4.6 The Developing World

Biotechnology is an affordable technology and if applied sensitively is capable of delivering significant benefits to countries with less developed agricultural systems. For example, the introduction of stress tolerance characteristics will improve the reliability of yields by helping crops withstand extreme conditions, new disease and pest resistance traits will help reduce crop losses, and genetic improvement of local crops and livestock can be accelerated through the use of genetic maps and marker-assisted breeding programmes.

5. THE BUSINESS ENVIRONMENT

The contribution of biotechnology to the competitiveness of UK agriculture, and associated industries, could be limited by the lack of harmonisation of regulatory controls between Britain, Europe and the rest of the world.

5.1 Safety Controls

The first priority of the regulatory framework must be to guarantee protection of the consumer and the environment, but should not be an unnecessary burden on industry, nor discourage beneficial development. Government must ensure that a competitive environment exists.

Differences currently exist in the regulations concerning the approval of applications of biotechnology. The process for safety approval of foods derived from genetic modification in the UK and the EU differs from that in the USA. There is also variation in the regulatory control of releasing genetically modified organisms into the environment. Lack of harmonisation will continue to impede the development of biotechnological industries both within the UK and internationally. The NFU therefore believes that co-ordination of regulatory controls is essential to maximise regulatory efficiency.

Action is already being taken to develop and co-ordinate international policy in this area by the United Nations Environmental Programme, the World Health Organisation (WHO), the United Nations Food and Agriculture Organisation (FAO), the Organisation for Economic Co-operation and Development, and Codex Alimentarius.

5.2 Patenting

The NFU is sensitive to the concerns of underdeveloped and developing countries on the possible exploitation by multinational companies of products derived from their naturally occurring flora and fauna. The NFU supports attempts to develop international legislation in this area.

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Following many years of negotiations, and the failure of the 1995 draft EC Directive for the Legal Protection of Biotechnological Inventions because of ethical objections, a new version of the legislation is again under consideration. The aim of the Directive is to harmonise the intellectual property laws of member states. The Directive was revised and again presented to the European Commission and Parliament in 1997 and has still not been approved. It now includes satisfactory clauses which give derogations for farm use, and should allow farmers, and the companies producing GM products, to benefit from them.

The NFU considers that the absence of a harmonising directive hampers the competitiveness of British industry and urges the EC to pass satisfactory and appropriate legislation as soon as is practical.

6. CONCERNS

Whilst biotechnology is already highly regulated, there are a number of concerns: the likely impact on the environment; the practical problems which face farmers, growers and the food industry; the concentration of power and control of biotechnological applications on the input side of agriculture in the hands of a few multinational agri-food companies; and, the public attitudes toward this new science.

6.1 *Changes to the Natural Environment*

Those intending to conduct an experimental release or to market a genetically modified organism (GMO) must obtain consent from the Secretary of State for the Environment, who is advised by the Advisory Committee on Releases into the Environment (ACRE)¹. In order for consent to be granted safety and risk is evaluated.

The NFU believes that the regulatory controls do not take sufficient account of all the potential environmental *post-release* hazards and their implications when genetically modified plants are grown on a commercial scale. There is the possibility that genetically modified crop plants will spread into the natural environment, or that gene transfer into wild species by cross pollination will occur. This is considered genetic pollution by some environmentalists and could lead to an erosion of genetic diversity if "foreign" genes replace those already present in native plants. Field trials indicate that the likelihood of a genetically modified crop spreading into a natural environment is no different from that of the conventional crop from which it is derived. Other field trials show that cross pollination is inevitable but that the significance of it depends on the crop species being used, and the types of weed or wild plants that naturally occur in the environment.

Other concerns relate to the effects that herbicide tolerant genetically modified (GM) crops, or GM crops that contain a natural pesticide, will have on the environment. For example, a more complete destruction of weed species at field margins and hedgerow bottoms could reduce the habitat availability for insects. Also, if herbicide resistant volunteers become a problem in following crops, a less acceptable herbicide may have to be used to control them. Both of these results could cause a reduction in the numbers of birds and other predators that rely on the weed and hedgerow environment and the animals that live therein. In a similar manner, a more effective method of killing systemically feeding insect pests will reduce the availability of food for predators. A balance needs to be struck between the legitimate desire of farmers to provide a livelihood for themselves and their families and the continuing need to maintain a sustainable environment for future generations.

More worrying are studies that suggest that some GM pesticide-containing crops may affect the longevity and fecundity of predator insects, such as ladybirds, or may affect the behaviour of pollinators, such as bees. Also, the attainment of resistance by pest insects to the Bt toxins may ultimately reduce the usefulness of such GM crops. Other concerns relate to the possible transfer of genes between plant viruses and their hosts. There is relatively little information on the relationships of plant viruses and the field environment, so if such transfers do occur the significance of them cannot yet be accurately forecast. In general it can be said that scientists do not have a complete understanding of natural ecosystems. It is therefore impossible to predict accurately the effects of large scale release of genetically modified organisms.

The NFU is seeking further clarification about what might be considered "harmful" to the environment, or how any "harm" will be observed and quantified. Moreover, whose responsibility is it to ensure that "harm" does not result, and on whom does legal liability fall if it should?

The NFU is concerned that there is currently no requirement for monitoring environmental change after consent to market has been granted. However, it is recognised that widespread monitoring would be very difficult and costly. It is also acknowledged that a condition of consent to market a GMO requires the applicant to inform the Secretary of State of any environmental problems that subsequently occur. Nevertheless, the NFU believes that this requirement is not adequate to ensure that any environmental change will be observed and acted upon.

¹ Genetically modified organisms are regulated by the European Directives 90/219 (Contained Use) and 90/220 (Deliberate Release) which is implemented in the UK by the Genetically Modified Organisms (Deliberate Release) Regulations 1995, under the Environmental Protection Act 1990.

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Governmental should therefore be proactive in setting up a process of post-release monitoring of newly approved commercial growing of GM plants.

The NFU think that the monitoring programme should be independent of the company that is expected to profit from it, should be paid for by government, and should either be directed by government, or under government contract. We believe that this post-release monitoring programme should last for a 10 year period and that the review that follows should form the basis for the continued licensing of the GM crop. The report and data that arise form the monitoring programme should be in the public domain. Any severe environmental changes that arise within the monitoring period could lead to immediate withdrawal of approval. Prompt action would then have to be taken to limit environmental damage if such an event occurred. The NFU has noted that suggested changes to EC Directive 90/220 on deliberate releases of genetically modified organisms into the environment has included a provision for a mandatory monitoring of products after their placing on the market, which will be linked to a consent granted for a fixed time period of seven years. These proposals generally correspond with NFU proposals in this area.

The NFU believes farmers will continue to have an important role to play in observing any changes in the agricultural environment. A clear regulatory framework would help them properly to fulfil this role.

Further ecological research should therefore be a priority, in order to improve our understanding of natural ecosystems and the implications of releasing novel organisms into them.

6.2 *Agricultural Controls*

During the approval process ACRE considers the environmental hazards of the genetically modified organisms submitted to it. ACRE evaluates the likelihood of a hazardous event occurring and its possible impact on the environment. However, the NFU continues to recognise that ACRE's remit is limited and we believe that some wider issues should be formally considered by regulators and advisory committees with appropriate expertise. One example of such a problem would be that of the development of herbicide tolerant plants, and whether the use of such plants is a good strategy for weed control both environmentally and agronomically in the long term. An integrated system, applying principles similar to those applied to agrochemical approvals, might be appropriate, and deserves further consideration.

Under current regulatory controls, responsibility for the sensible use of the technology falls to the farmer, whose decision making is influenced by numerous socio/economic and environmental factors. Furthermore, it is important not to under-estimate the influence of the commercial companies supplying production inputs to the farmer, nor the specified requirements of the processors and manufacturers who will purchase the end product. In order to ensure that the technology is used responsibly it is essential that explanatory information is provided to the farmer. Information is necessary to explain how to use the product and to identify potential risks.

In view of this the NFU, in association with the British Society of Plant Breeders and the United Kingdom Agricultural Supply Trade Association, in 1997 produced codes of practice that relate to the provision of information for genetically modified crops. The main features of the codes are the requirement for a clear identifier that a seed is genetically modified to be placed on all seed packets/sacks. This should be supplemented by more detailed information supplied in a leaflet that accompanies the seed, sales literature, and the National Institute of Agricultural Botany recommended lists. The explanatory information should provide details of the specific genetic modification, and should give details of the agronomy of the GM plant. Farmer training schemes may also be necessary. When the crop is harvested the produce should be segregated from that of non-GM crops. Each GM crop consignment should be accompanied by a post-harvest declaration, which should include the name of the variety. The provision of such information should be maintained during subsequent transportation. These codes of practice will require detailed record keeping both on and off farm, which will form the basis of traceability of the crop.

6.3 *Practical Considerations*

The NFU has examined the practical problems which the farmer and grower may face as a result of growing genetically modified crops. For example:

- Herbicide tolerant volunteers;
- Reduced efficacy of agrochemicals;
- Cross contamination between GMO and conventional crops.

Herbicide tolerant crop varieties will lead to herbicide tolerant volunteers in future crops on that land. Volunteer oilseed rape in arable crops is already posing an increasing problem to UK farmers. Herbicide tolerance may compound this problem and increasingly limit crop rotation and management systems.

Through genetic modification, herbicide tolerance is being incorporated into many crop species, such as soya, maize, oilseed rape, and sugar beet. Widespread use of these herbicide tolerant crops might result in over reliance

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on one herbicide, or a few such herbicides. This will increase the selective pressures on the weeds which may accelerate the development of resistance to the herbicide.

There is also the possibility that a gene conferring herbicide tolerance could be transferred to weed species by natural cross breeding. Tolerance to the herbicide might then spread through the weed population. The spectrum of weeds controlled by a particular herbicide would be reduced, limiting the efficacy of that agrochemical. A more severe complication of this might be that of gene "stacking", where the genes for tolerance to several different herbicides become concentrated in one weed species. Obviously, other herbicides would be available to control volunteers and weeds, but these may be less "safe" and increase the complexity of weed control.

Oilseed rape volunteers in a future crop of a different variety will result in cross-contamination, affecting the marketability of the crop. Although this problem is not new, it is likely to be increasingly important as new types of "designer" oilseed rape, with specific oil profiles for industrial use, become commercially available. Controlling such volunteers may be difficult. Methods of zoning¹ or isolation may be necessary. These are unpopular, difficult to implement and will reduce the flexibility of land use.

Another concern was highlighted by the decision of the US Environmental Protection Agency (EPA) in 1998 to reduce the level of the herbicide bromoxynil to which humans can be exposed. The EPA rules state that human exposure must be 100x less than the lowest concentration shown to cause birth defects and cancer in laboratory mice. A bromoxynil tolerant GM cotton plant passed this test and in 1997 170,000 hectares of it were planted in the USA. The EPA changed the acceptable levels to a tenth of that previously used because pregnant women and infants are considered to be at extra risk. Residues of bromoxynil on fields planted with the GM cotton have been said to exceed this lower threshold. Assuming that the reduced levels are upheld by the EPA Scientific Advisory Committee the GM cotton may have to be withdrawn from the market.

The NFU believes that advisory panels should take account of these wider implications when granting consent to market.

6.4 Animal Welfare

The NFU acknowledges that genetic modification of animals raises greater moral and ethical concerns than genetic modification of plants or micro-organisms.

There are currently four main areas of research where the use of genetic modification of animals is being investigated. These are disease and parasite resistance, growth promotion, the use of livestock for pharmaceutical production, and for supplying organs for transplantation to humans (xenotransplantation). Biotechnology might be used to enhance an animal's resistance to specific diseases. Marker-assisted breeding can be used to transfer naturally occurring disease resistances into commercial livestock, but in some cases efficient resistance may only be achievable by genetic modification. Such developments must deliver positive health benefits without compromising animal welfare. Some initial research into enhancing productivity of livestock through genetic modification resulted in unexpected deleterious effects (although these have since been overcome).

The third area of interest is pharmaceutical production. Therapeutic proteins which cannot easily be synthesised *in vitro* can be synthesised by genetically modified animals. This technology can be valuable for producing human and veterinary pharmaceuticals and vaccines. An example of this is the production of α_1 -antitrypsin extracted from the milk of a herd of transgenic sheep that is being clinically tested as a treatment for cystic fibrosis. It should be pointed out that altering milk composition can also be done for human nutritional reasons. Another possible use of transgenic animals is to use them as models for the study of animal or human diseases.

The final area is that of xenotransplantation. This area was extensively explored by the Advisory Group on the Ethics of Xenotransplantation. Their report entitled, "Animal Tissue into Humans" was published in 1996. They concluded that there were no particular ethical objections to the use of animal organs for human transplantations. However, they concluded that the use of primates for such purposes should be precluded because of the risk of disease transfer to humans. They also recommended that a two year moratorium be put on actual animal to human transplants to try to determine what risks of disease transfer, if any, there are in practice. Recent studies of the retroviruses of pigs, the animals that are expected to be the most likely organ donors, have shown that some viruses are intimately integrated into the pig's genome. This means that producing virus-free pigs may be impractical. This issue will have to be thoroughly evaluated before pigs, or for that matter other mammalian species, are used for transplantation purposes.

The development of cloning technology, and its application to animals such as cattle and sheep, has raised other issues. One of the first is that cloned animals have proved to be much larger than non-cloned ones, with the animal welfare considerations that this has raised for the mother of such animals. Another problem that could arise would be if cloning was so widespread as to result in an unacceptable level of inbreeding. However,

¹ Zoning is the registering of a known locality where, for example, only one type of "designer" oil may be grown.

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theoretical studies suggest that this problem could be limited. On the beneficial side cloning could be used as a useful technique to aid in the preservation of rare breeds. Nevertheless, the NFU expects that in due course cloning will become one of many accepted techniques for livestock reproduction.

The report of the Banner Committee on The Ethical Implications of Emerging Technologies in the Breeding of Farm Animals closely investigated a range of techniques from selective breeding to genetic modification. Amongst its recommendations, the Committee called for a number of techniques to be considered further by the Farm Animal Welfare Council. The NFU supported this recommendation. Government must ensure that applications of new technologies do not lead to animal welfare problems.

6.5 Antibiotic-Resistant Marker Genes

One of the first genetically modified crops that was adopted for commercial planting was Novartis's Bt maize. This contained an antibiotic-resistant "marker" gene. The Advisory Committee on Novel Foods and Processes (ACNFP) recommended against the authorisation of this product for growing in the UK or Europe because of the perceived risk of the "marker" gene being transferred to the bacterial inhabitants of the gut of livestock, with eventual possible transfer of antibiotic resistance to human pathogens. This risk was considered to be low but it was felt that further investigations were warranted before the use of the maize was acceptable. This recommendation was eventually overturned by the EC, which led to considerable public protest. The whole matter is still not resolved as this document is written, as various legal and technical challenges to the decision have not yet been resolved. Because of these concerns it is the policy of the NFU that such "marker" genes not be included in genetically modified crops in the future. They are felt to be unnecessary, as consumers are reluctant to accept them, and alternatives are available.

6.6 Minor Crops

Conventional crop protection methods often neglect the needs of minor crops due to the high cost of obtaining a licence compared with the relatively low expected financial return. The biotechnological techniques for disease and pest control already developed for major crops such as maize and soya, offer enormous potential for the protection of horticultural and other minor crops. There is need for agrochemical companies to license generic technologies in their use in minor crop development. Examples of these would be herbicide tolerance and pesticide inclusion. The government should also fund basic research to ensure that these new technologies can be transferred to minor crops which currently have little or no protection. This could be vital to the future viability of such crops.

6.7 Imports

Imports of the GM commodity crops soya and maize have led to considerable public unease. The lack of segregation and consequently labelling has led to a situation where it will need a considerable effort for a consumer to avoid eating food that does not contain genetically modified components. Together with retailers and other UK bodies the NFU think that this situation is unsatisfactory. Ideally, international acceptance of data, and recognition of safety evaluation procedures, might counter these concerns. At the moment UK producers could be competitively disadvantaged as regulatory controls have not been harmonised, and appear unlikely to be in the near future.

7. FOOD AND THE CONSUMER

British farmers and growers aim to meet consumers' requirements by producing a variety of safe, fresh, wholesome and competitively-priced food. Consumers must have confidence in the food they eat, and in the regulatory system which protects their interests. Any loss of public confidence would be serious for consumers, producers and the food industry alike.

7.1 Public Perception

Consumer research shows that the public has reservations over the use of biotechnology in food production. Attitudes vary according to the application. For example, applications involving genes derived from plants are perceived more favourably than those involving genes derived from animal sources.

Public perception will be a significant influence in the uptake of the technology by food manufacturers and retailers. Application of biotechnology could be used to enhance the value of a brand, such as the Flavr Savr tomato paste. However, in other cases a poor perception of the application could damage the brand image. In such a case this could also damage public perception of the corresponding conventional product.

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7.2 Food Safety

The NFU's existing Food Policy States:

- the approval of new products must be based on sound scientific criteria and a clear understanding of the nature of the food and its safety hazards;
- legislation must be clear, practicable and enforceable;
- food safety controls should be harmonised internationally.

In Europe all foods derived using the process of genetic modification are regarded as "novel". The EC Directive on Novel Foods and Novel Food Ingredients was enacted in May 1997. The Directive seeks to harmonise controls in Europe. One difficulty with the legislation is that a food is only considered to be a "novel" one, and so covered by the legislation, if it is "*no longer equivalent*" to an existing food. Unfortunately the term "no longer equivalent" is not clearly defined and this can lead to uncertainty. In addition, while a particular food may not be covered by the novel food regulations, there can be consumer concerns about how the product has been produced.

We are concerned that products of biotechnology (genetic modification in particular) are reaching the market in Europe before harmonised controls are in place. The NFU believes that international guidelines for safety assessment are crucial and supports the programme being developed by the WHO/FAO to compare and co-ordinate international policies on this matter.

The NFU believes that the safety assessment procedure carried out by the ACNFP provides adequate protection to the consumer. Openness is essential for building and maintaining public confidence in products of biotechnology. The approval process should be transparent and include consumer consultation.

7.3 Labelling

Product labelling and further explanatory information is vital in ensuring that consumers can make an informed choice. A careful balance should be maintained between the information supplied on food labels and information provided from other sources to assist the consumer in understanding and interpreting these labels. Food labels should be clear, simple, truthful and meaningful. Misleading or confusing claims are unacceptable, do not serve the public interest and are commercially counter-productive.

Some consumers have moral and ethical concerns about foods derived from genetically modified organisms. In 1992 the Ministry of Agriculture, Fisheries and Food appointed a Committee to consider the moral and ethical concerns of such food products. It recommended that genetically modified foods containing "copy" genes of human origin or genes derived from animals should be labelled to allow consumer choice.

The government's Food Advisory Committee also reviewed guidelines for labelling food produced using genetic modification in 1993. They recommended that food should be labelled where:

- It contains a gene originally derived from a human or an animal which is subject to religious dietary restrictions;
- It is plant or microbiological material containing genes derived from human or animal sources.

The Group of Advisers on the Ethical Implications of Biotechnology of the European Commission, in May 1995, presented the opinion that labelling will be appropriate where modern biotechnology has led to a substantial change in composition, nutritional value or the use for which the food is intended. In such cases the label should specify not only the nature of the change but also the process used to achieve the change (e.g., genetic modification). If the product has not been substantially changed, it will not be appropriate to label.

The food industry recognises that these guidelines provide only a baseline requirement. In order to ensure informed consumer choice labelling should go further than these guidelines. The NFU worked in association with the Institute of Grocery Distribution (IGD), who in 1997 produced a set of voluntary guidelines for the labelling of genetically modified foods. The announcement that these guidelines will be introduced for 1998 was made by the IGD, in association with the British Retail Consortium and the Food and Drink Federation (FDF) on 20 November 1997. Since then a draft EC Directive has been produced that relates to food that contains soya and maize. Labelling will use the specific wording of "produced from genetically modified soya/maize". Products can be labelled as not containing GM soya/maize as long as there is scientific analysis to support the claim. The third category is "may contain" GM soya/maize. The contents of this EC Directive has proved to be controversial and it is unclear whether it will be approved in its present form.

Labelling regulations will ultimately need to be decided at European level, and be further incorporated into national legislation. They will also have to apply not just to foodstuffs, but also to animal feed.

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7.4 Provision of Information

Consumer reaction to the use of biotechnology in food production will be determined by many factors, such as perception of benefits and risks, knowledge, understanding and perceived freedom of choice.

Food labels and appropriate supplementary information will be important factors in achieving understanding, maintaining confidence and allowing an informed choice. The provision of information alone may not improve public acceptance but it will allow consumers to make informed choices.

The NFU recognises that there is a need for improving public understanding. Balanced and impartial information should be provided by government and the food industry. The Ministry of Agriculture, Fisheries and Food is commended for its *Foodsense* series of publications. Other useful booklets have been produced by the Biotechnology and Biology Sciences Research Council and the FDF. Further similar initiatives should continue.

The NFU also supports food industry initiatives to develop communication strategies in order to improve public understanding of the technology and its applications. The NFU believes retailers are best placed to disseminate information to consumers and many of them have produced explanatory leaflets on biotechnology or specific aspects of it. Other explanatory leaflets have been produced by the IGD.

It is important for the food industry itself to gain a greater understanding of biotechnology and consumer perceptions of biotechnology. The NFU recognises the importance of consumer science research, such as that carried out by the Institute of Food Research, and will continue to encourage research into this area.

The NFU will continue to urge all levels of the food chain to develop effective communication strategies in relation to biotechnology.

8. RECOMMENDATIONS FOR FUTURE NFU ACTION

8.1 Encourage the international harmonisation of regulations controlling safety of biotechnology products.

8.2 Ensure the principle of farmers' privilege is incorporated into the final version of the EC Directive for the legal protection of biotechnological inventions.

8.3 Seek clarification of liability for any environmental harm resulting from release to the environment of genetically modified organisms.

8.4 Promote the introduction of a statutory regime of post-release monitoring of commercially grown genetically modified crops.

8.5 Urge government to consider formally certain wider environmental and farming implications when considering granting consent to market.

8.6 Ensure farmers are provided with all necessary information to allow the responsible use of the technology.

8.7 Encourage openness and consumer consultation during the approval process.

8.8 Continue working closely with other levels of the food chain in order to develop a suitable food labelling system for foods derived from genetic modification: and ensure that any system does not cause any unnecessary bureaucratic or logistical problems for food producers.

8.9 Work with government and other levels of the food chain to improve public understanding of biotechnology.

9. Encourage research to improve understanding of public perception of food and biotechnology.

9.1 Ensure that government research funding is maintained, so that the UK and its farming industry stay at the forefront of developments.

10. SUMMARY

10.1 *Biotechnology could improve the competitiveness of UK agriculture in a variety of ways such as:*

Reduced unit costs of production through:

- Increased yields
- Reduced expenditure on herbicides and pesticides
- Reduced losses through disease

New crops and new crop uses offering wider market opportunities for:

- Industrial feedstocks
- Biofuel
- Pharmaceutical production
- Novel foods

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Improved marketability of existing products, such as:

- Improved taste, texture and keeping properties
- Increased uniformity of products
- More desirable processing qualities, less waste for the food manufacturer

Efficacy of disease control through:

- Reduction in pest damage
- Diagnostic tests

Improved animal health and welfare through:

- In-built disease and parasite resistance
- Novel vaccines
- Diagnostic kits

Biotechnology may also offer environmental benefits through:

“Cleaner” raw materials for industrial processes

Energy recycling through biofuel production

Bioremediation of contaminated land

More targeted pest/disease control reducing the amount of chemical inputs

And offer benefits to the developing world through:

Improved stress tolerance in crops

More effective disease and pest control

More efficient genetic improvement of local crops and livestock

10.2 *The contribution of biotechnology to the competitiveness of UK agriculture and associated industries could be limited by:*

lack of harmonisation of regulatory controls between Europe, North America and the rest of the world

- patent law, in particular, scope of patents
- Food and environmental safety controls

Public perception of biotechnology

- Fear of unknown
- Perceived benefits and risks
- Possible rejection of technology

Farmers, growers and the food industry failing to adopt new products

10.3 *The NFU has a number of concerns relating to some users of biotechnology:*

Commercial competitiveness of UK agriculture could be damaged if biotechnology developments were to be taken up by competitor countries but not by the UK.

Implications for the wider environment

- Incomplete understanding of natural ecosystems
- Insufficient requirement for monitoring after consent to market
- Potential reduction in natural biodiversity
- Unclear liability for any environmental harm

Practical concerns for farmers

- Herbicide tolerant volunteers
- Reduced efficacy and availability of agrochemicals

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[Continued

- Cross contamination of industrial and edible oil crops
- Lack of a system to ensure responsible use of the technology
- Insufficient mechanism for withdrawal of approval
- Animal welfare implications
- Possible affect on public perception of conventional products
- International marketing problems

THE NFU BIOTECHNOLOGY WORKING GROUP

Mission Statement

The Biotechnology Working Party aims to develop an understanding of the issues surrounding biotechnology, their implications to agriculture and horticulture and to make recommendations to the Council of the NFU on biotechnology policy.

Terms of Reference

The Biotechnology Working Party will consult with and co-ordinate the views of interested committees, groups and relevant organisations.

Membership

Tim Bennett, NFU Deputy President, and Welsh dairy and livestock farms.

Ben Boot, OBE, Chairman of the NFU Biotechnology Working Party, member of the NFU Milk Committee and a Shropshire dairy farmer.

Dr David Carmichael, member of the NFU Sugar Beet Committee and Lincolnshire arable farmer.

Dr Oliver Doubleday, Member of the BBSRC Strategy Board, and Chairman of the NFU Parliamentary, Land Use and Environment Committee, and a Kent horticultural, sheep and arable farmer.

Bob Fiddaman, member of the NFU Oilseeds Committee and a Hertfordshire arable farmer.

Ross Kenyon, representing the poultry industry.

John Lampitt, former Chairman of the NFU Public Affairs Committee and a Warwickshire arable farmer.

Archie Montgomery, member of the NFU Cereals Committee and a Somerset arable farmer.

Dr Graham Plastow of Dalgety plc and PIC Group.

Bob Uglow, a Buckinghamshire dairy farmer.

Piers Verey, member of the NFU Glasshouse Produce Committee and a Hampshire horticulturist.

APPENDIX 4

CODE OF PRACTICE ON THE PROVISION OF INFORMATION RELATING TO GENETICALLY MODIFIED CROPS

INTRODUCTION

Modern plant biotechnology extends the scope and precision of conventional plant breeding. Techniques such as genetic modification (GM) offer significant improvements in crop production and utilisation, with benefits to agriculture, the food industry, consumers and the environment.

The provision of information relating to genetically modified crops will play an important role in ensuring best practice is adopted by all those involved in the production, handling, storage, processing and marketing of these products.

An effective information delivery system along the food supply chain for UK-produced GM crops is also needed to provide consumer choice and satisfy consumer demands for information about the use of GM in food production.

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[Continued

This Code of Practice has been developed to establish a consistent, industry-wide approach to information supply for GM crops from seed to primary end-product. This will provide the information required by those further along the food chain to manage storage and processing operations effectively, to conserve the value of the harvested commodity and to ensure appropriate record-keeping and onward transfer of information.

THE FOLLOWING BASIC PRINCIPLES SHALL APPLY:

All GM material entering the food chain must comply with legal requirements relating to environmental release, marketing consent and food safety.

All parties must take reasonable steps to ensure that the information provided is accurate and presented in a clear, concise and readily understood format.

This Code of Practice will be subject to annual review.

INFORMATION REQUIREMENTS

Plant breeders are required to identify and provide comprehensive information relating to GM crop varieties to comply with the requirements of statutory trials within the EU. This information is publicly available through independent published sources such as the EU Common Catalogue and national recommended and descriptive lists.

To ensure best practice across all sectors of the industry, and to provide traceability for individual consignments of GM varieties, the consenting parties (BSPB, NFU, UKASTA) recognise the need for successive transfer of supplementary information at strategic points along the food chain:

- *by seed merchants:* to market GM varieties and advise growers of the unique features of the material;
- *by growers:* to manage seed handling and crop husbandry effectively, to ensure appropriate record-keeping and storage arrangements and to market the harvested crop;
- *by merchants and wholesalers:* to ensure appropriate record-keeping and transfer of information during storage and onward distribution.

To comply with the requirements and objectives of this Code of practice, the licensor of the GM technology and/or developer of the variety should ensure that the following information is available to growers—either directly or via the seed supply trade—in relation to each GM crop variety:

The variety is genetically modified

The nature of the modification(s)

Specific husbandry and management advice

INFORMATION TRANSFER—SEED SUPPLIER TO FARMER

A combination of communication routes will be required to ensure that the necessary information is available to the relevant personnel and in an appropriate format at each stage in the seed marketing and primary production process:

1. *Variety Guides*

Independent UK variety guides will identify which varieties have been developed using genetic modification and, in each case, the nature of the modification(s).

2. *Marketing Literature*

Commercial sales and marketing material produced by the licensor of the GM technology and/or the developer of the variety should state clearly that a variety has been developed using genetic modification and the nature of the modification(s). It should also provide basic advice on good husbandry and farm management practice, particularly where this differs from conventional crops, as well as details of where further advice can be obtained (e.g., Information Helpline).

3. *Seed leaflet*

All growers purchasing GM seed should receive an explanatory leaflet stating clearly that the variety has been developed using genetic modification and the nature of the modification(s). It should also provide basic management advice relating to handling, storage and transportation of the seed, as well as details of where additional management and husbandry advice can be obtained (e.g., Information Helpline).

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4. *Seed package identifier*

A visual identifier, exclusive to GM varieties, should be clearly displayed on the label of each package of GM seed. This will help to ensure that the seed is handled and stored on-farm according to best management practice, and to inform farm personnel that supplementary management and husbandry advice is available.

5. *Information Helpline*

The licensor of the GM technology and/or developer of the variety should provide a telephone information service to answer specific requests for more detailed information from growers and/or the seed supply trade relating to the product and its use.

GOOD AGRICULTURAL PRACTICE

To comply with the requirements of this Code of Practice, each GM crop should be identifiable by variety at all stages, from initial seed stock through production, harvesting and storage.

The importance of good agriculture practice, including record-keeping and segregation of varieties, is recognised by growers as a vital component in meeting the quality assurance demands of the food industry and, ultimately, of consumers.

The NFU will continue to communicate the importance of record-keeping to its members. Other information supplied to farmers in relation to GM crop varieties should also highlight the significance of record-keeping in safeguarding the value and integrity of the harvested commodity, and in transferring information further along the food chain.

Basic guidelines for good agricultural practice when growing GM crops with specific agronomic traits should be encouraged. Summary guidelines, where developed, should be followed in combination with variety-specific information.

INFORMATION TRANSFER—EX-FARM

When transported off the farm to the merchants and wholesalers, each GM crop consignment should be accompanied by a post-harvest declaration which should include the name of the variety.

The provision of such information should be maintained during subsequent transportation of consignments. Those involved with GM crops post-farm should address the issues of continued transfer of information and traceability of such crops. In addressing these and other points attention should be paid to the basic principles contained within this document.

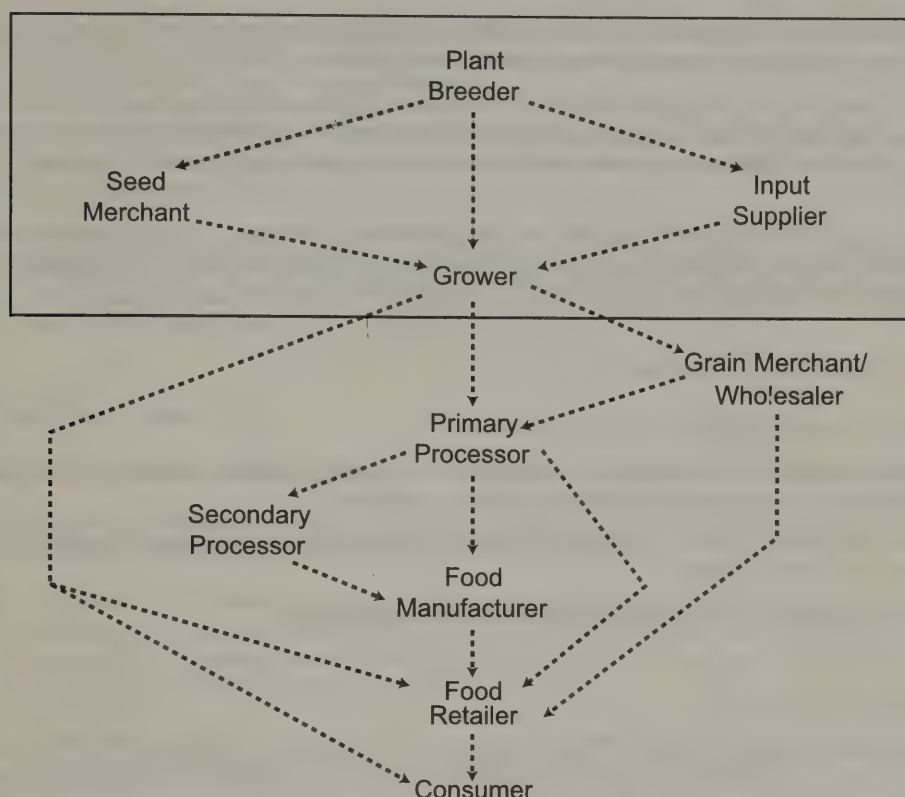
INFORMATION FLOW FOR UK-GROWN GM CROPS

The flow chart below identifies the strategic points along the crop-based food supply chain at which information transfer will be required to ensure the aims of this Code of Practice are fulfilled. The boxed section illustrates the role of this Code of Practice, which fulfils the information requirements of the primary supply chain from seed supplier to primary end-product.

Organisations further along the food chain, from primary processors to food retailers, are encouraged to ensure that the successive transfer of information is maintained. This will enable the industry to comply with statutory food labelling requirements, and to provide supplementary consumer information on a voluntary basis.

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This Code of Practice has been agreed jointly by BSPB, NFU and UKASTA in consultation with other interested organisations including the British Agrochemicals Association, the British Sugar Beet Seed Producers Association and the Institute of Grocery Distribution.

April 1997

CODE OF PRACTICE TO ESTABLISH A CONSISTENT APPROACH TO PROVIDING INFORMATION TO FARMERS AND GROWERS REGARDING GENETICALLY MODIFIED CROPS

January 1997 (Revised June 1997)

This document has been drafted by the National Farmers' Union following consultation with the British Society of Plant Breeders.

The aim is to encourage best practice among farmers and growers who choose to grow genetically modified crops. In order to achieve this it is imperative that they receive sufficient pertinent information about these new crops.

This code of practice seeks to ensure that a consistent approach to provision of information is adopted by the seed supply industry. It details the type of information that should be provided to farmers and growers, and how that information is best communicated.

There is also a clear need for consumer information regarding food containing genetically modified material. Food Labelling will play an important part in informing consumers and providing consumer choice. Labelling food products will be on a statutory and voluntary basis. It is essential that an effective information supply system is provided all along the food chain from primary producer to the retail point of sale. This code of practice seeks to ensure that this information system is in place.

CODE OF PRACTICE TO ESTABLISH A CONSISTENT APPROACH TO PROVIDING INFORMATION TO FARMERS AND GROWERS REGARDING GENETICALLY MODIFIED CROPS

National Farmers' Union

1. Introduction—The need for information

The National Farmers Union and the British Society of Plant Breeders have recognised that the appropriate use of genetically modified crops will be the responsibility of farmers and growers. They therefore need to

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[Continued

receive sufficient pertinent information, to ensure that they are sufficiently informed of how to use the products and are aware of any necessary changes to farm management practices.

Provision of clear, relevant information along the food chain is necessary to ensure that food businesses can fulfil their food labelling obligations (whether statutory or voluntary). This will require a continuous information supply chain from plant breeders and seed merchants, to farmers and growers, merchants and wholesalers and retailers.

A consistent approach by industry is highly desirable, especially in the early years of commercialisation of genetically modified crops varieties. The adoption of this code by the seeds industry will ensure that the benefits of this new technology are realised, and that confidence in its safety is gained.

2. Who needs information on the farm?

Information is needed at three levels in farm operations:

- (i) *The manager or owner*, who is responsible for cropping policies, making the seed purchasing decisions and selling the final crop on to their customers;
- (ii) *The unit manager* who is organising the implementation of the cropping programme and takes possession of the seed;
- (iii) *The operator* who will be undertaking the day to day operations.

3. What information is needed?

- (i) Farmers and growers need to know that *the seed is genetically modified*. This will ensure that information which may be required by the end consumer, is available throughout the supply chain. It may be necessary to label the end food product to identify that it contains genetically modified material. This information must therefore be available at the point of primary products so that it can be passed onto customers and ultimately to the final consumer.
- (ii) Farmers and growers need to be informed of *the nature of the modification*. This will ensure that the farmer is able to make an informed decision when purchasing seed, and to provide information to allow him to make any necessary adjustments to farm management practices.
- (iii) Farmers and growers may require further *advice on good farm management practice*. For certain genetically modified products, such as herbicide tolerant crops, or crops modified for industrial purposes, special management conditions may be required. Clear advice on any necessary changes to farm practices is needed, including why such changes are necessary, and what problems might occur if these changes are not implemented. Advice should cover management of potential volunteer problems, minimising cross-contamination both in the field and in storage, and accidental spillage during haulage.
- (iv) Farmers and growers should be made aware of *the importance of record keeping*. Long-term record keeping will become increasingly important with the introduction of genetically modified herbicide tolerant and "designer" oil crops. This will be particularly important where farms or parcels of land are managed on short-term contracts. The importance of record keeping, to minimise problems in the future, needs to be highlighted by the supplying companies.
- (v) Farmers and growers may also require *supplementary information and advice* on management practices. Companies supplying genetically modified crops should offer their customers an additional information and advice service.

4. How should information be communicated?

A combination of communication approaches will be needed to ensure that the appropriate farm personnel receive sufficient, pertinent information that is easily understood. The necessary communication approaches, over and above normal sales and marketing literature, should include:

- (i) *Explanatory information in sales literature and the NIAB handbook*. In making a purchasing decision, a manager or owner will be relying on information provided by commercial marketing material and the NIAB handbook.
- (ii) *Explanatory information in a leaflet accompanying the seed*. The unit manager and the operator will rely on the information provided with the seed.

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[Continued

- (iii) *An identifier on seed sacks.* An identifier on the seed sack is necessary to alert farm personnel to the supplementary information, and to ensure that farm operators do not unwittingly mix genetically modified and conventional seed before sowing.
- (iv) *An information help-line.* While making a purchasing decision, or making adjustments to management practices, a farmer may require supplementary information and advice. A telephone information service should be provided by product suppliers.

The information provided ((i) and (ii) above) should not be too detailed. It does not need to offer in-depth "best-practice", merely to alert all concerned to any differences from conventional crops, and any adjustments to management practices that are necessary. More detailed information can be provided to farmers through an information "help-line".

5. The information required

The necessary information should be communicated to farmers and growers as "good farm practice".

- (i) *Good Farm Practice.* Farmers must be aware of the nature of the modification, and be aware of any special management practices that might be necessary.

The use of crops genetically modified for herbicide tolerance will inevitably lead to herbicide tolerant volunteers in subsequent crops. They may persist for many years after the crop has been grown commercially. Farmers must be aware of any possibility and be provided with management advice on how best to minimise possible problems.

Advice should cover seed handling, storage and transportation. The importance of segregation from conventional varieties and the need for due diligence should be highlighted.

Long-term record keeping will become increasingly important as farmers use crops genetically modified for herbicide tolerance and for industrial uses. For example, oilseed rape can remain in the soil for 10 or more years after the commercial crop is grown. Volunteers from an oilseed rape crop, genetically modified to produce an industrial oil, could lead to accidental cross contamination of oilseed crops grown in subsequent years, in the same, or adjacent, field.

It is therefore important that farmers record the location and nature of such crops, so that future cropping and treatments can be planned effectively. This will ensure that any potential cross contamination between oilseed rape crops can be avoided. Long-term records will be particularly important where land is farmed on a short-term contract basis. It is clearly in a farmer's interest to keep records and the need to do so should be highlighted as an integral part of "good farm practice" rather than as something additional.

The importance and relevance of long-term record keeping should be included in the explanatory information accompanying the seed, and in the NIAB handbook. The NFU will also play a role in highlighting the importance of record keeping to NFU members.

- (ii) *Information help-line.* By providing a telephone information service to farmers and growers, supplying companies will ease product introduction and help build understanding and confidence in the product and the technology in general.

Farmers may require more detailed information via a telephone help-line prior to making their purchasing decision, and after they have received the seed. The telephone number for any help-line service provided should be prominently displayed on marketing literature and on explanatory information accompanying the seed. We encourage supplying companies to provide this type of information service to farmers and growers.

- (iii) *Labelling Seed Pack.* It is important that an identifier is used on the seed package itself, in order to inform the farmer/farm operator that the seed is different from conventional varieties. It should also alert him to the accompanying information.

The identifier should be simple and consistent across different species and varieties. It should be located on the official section of the official label.

Further discussion is needed to determine the most appropriate identifier. Suggestions include a simple logo, or form of words. Any identifier must be factual, meaningful and should not be misleading.

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[Continued]

Source information	Identifier on seed sack	NIAB handbook	Sales literature	Leaflet accompanying seed	Telephone help-line
The seed is genetically modified	✓	✓	✓		
The nature of the modification		✓	✓	✓	
Advice on good farm practice			✓	✓	
The need for long term record keeping			✓	✓	
Detailed additional advice					✓
Telephone number of help-line			✓	✓	

GENETICALLY MODIFIED HERBICIDE TOLERANT CROPS

JOINT RESPONSE TO MAFF CONSULTATION

*National Farmers Union (NFU)**British Society of Plant Breeders (BSPB)**British Agrochemicals Association (BAA)**United Kingdom Agricultural Supply Trade Association (UKASTA)**British Sugar Beet Seed Producers Association (BSBSPA)*

The organisations listed above believe modern plant biotechnology, including genetic modification, offers major scope for progress in crop production and utilisation. The technology holds significant benefits for farmers, food producers, consumers and the environment. As UK agriculture moves towards a more free and open global trading environment, the advances made possible by this new technology will play a key role in maintaining the viability and competitiveness of our farming and food industries.

These five organisations, together representing the UK agriculture and supply sectors, recognise the need to demonstrate an open and responsible approach to the introduction and application of this new technology. To promote best practice in the production and use of genetically modified crops, an industry *Code of Practice on the Provision of Information relating to Genetically Modified Crops*, issued earlier this year, was developed jointly by BSPB, NFU and UKASTA following widespread consultation over a 12 month period.

This Code of Practice provides for the development of specific guidelines for good agricultural practice when growing GM crops with particular agronomic traits. Together with the Assured Combinable Crops Scheme and the MAFF Codes of Good Agricultural Practice, it therefore offers an appropriate framework within which to address the issues raised in the Ministry's consultation document on genetically modified herbicide tolerant (GMHT) crops.

The organisations listed above firmly believe that industry itself is best placed to develop practical guidance on the growing of GMHT crops but with a leading government involvement in the promotion and distribution of that guidance. This approach would support the existing comprehensive regulatory framework controlling the development and commercialisation of these products. Such an approach is in line with the Government's deregulatory policy and would allow for a more flexible and dynamic framework, responsive to new developments in the production of these crops either as a result of practical experience or technological advances.

The industry-sponsored Code of Practice on the Provision of Information has been well-received among potential users and consumers of GM crops and, in consultation with Government and other interested parties, forms a good basis on which to build flexible and appropriate guidance for the cultivation of GMHT crops.

Plans are already well-advanced to develop industry guidance for the on-farm management and cultivation of GMHT crops. The MAFF consultation exercise provides an opportunity for these guidelines to take account of the full spectrum of views on this issue.

Areas to be covered should be specific to GMHT crops, with cross-referencing to other documents and codes as appropriate, in particular the MAFF Codes of Good Agricultural Practice, the Assured Combinable Crops Scheme, and the industry-sponsored code on the provision of GM crop information.

These areas will include:

1. *Seed*

- (a) labelling of the seed sack or package, and information contained in relevant accompanying documentation, in particular to ensure that the GMHT variety can be readily identified by the operator to prevent inadvertent herbicide applications to non-tolerant crops;

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[Continued

- (b) provision of specific husbandry and management information to accompany the seed;
- (c) clearly identified contact advice points or helplines from which farmers can seek additional information.

2. Production

- (a) reference to principles of good agricultural practice when growing and harvesting arable crops;
- (b) guidance on recommended separation distances or voluntary "zoning" arrangements;
- (c) specific guidance on management of volunteers and outcrossing;
- (d) specific guidance on management of cropping plans and rotations;
- (e) guidance on timing of spray applications and/or use of field margin buffer zones.

(This section will take account of guidelines already prepared by the British Agrochemicals Association covering certain aspects of the production and management of GMHT crops).

3. Record Keeping

- (a) reference will be made to existing requirements for on-farm record-keeping and any additional data considered appropriate;
- (b) guidance on format of records, who should keep them and for how long;
- (c) advice on procedures for transferring records or making information available to others (in the case of short-term tenancies or when contractors are used, the provision of accurate, up-to-date farm records will be essential to ensure the effective management of GMHT crops).

4. Monitoring

- (a) industry guidance will consider the role of a post-approval monitoring or feedback system, particularly in the initial stages of the introduction of GMHT crops, to assess their performance and to provide early information.

The MAFF consultation document refers specifically to measures aimed at preventing the development of multiple tolerance in GMHT crops. Practical advice contained in these guidelines to minimise the risk of out-crossing and spread of volunteers will control the risk of involuntary build up of multiple tolerance in the cultivated and non-cultivated environment. The commercial introduction of crop varieties with multiple herbicide tolerance will be subject to stringent regulatory approval before release.

In developing this guidance, the organisations concerned will take account of any comments received by MAFF in response to the present consultation. It is planned to issue draft guidelines for comment, covering the areas outlined above, by 30 November 1997, with a view to securing final agreement by 31 December 1997.

Once issued, the guidelines will be subject to annual review, taking account of new developments in the technology, practical on-farm experience and the input of ongoing research and extension projects.

11 September 1997

Examination of Witnesses

DR VERNON BARBER, Food Science Adviser, Mr TIM BENNETT, Deputy President, Mr BEN BOOT, Chairman, NFU Biotechnology Working Group, and Mr ROBERT FIDDAMAN, Member, NFU Biotechnology Working Group, National Farmers' Union of England and Wales, called in and examined.

Chairman

263. Good morning. May I welcome you to the Sub-Committee and thank you very much for coming before us to give evidence on the important issue of genetic modification in agriculture. Before we proceed to our questions could I, first of all, thank you very much for the paper you provided us with, which was

interesting and forms the basis of some of the questions we want to ask you. May I ask you to introduce yourselves, not as an organisation but as individuals.

(Mr Bennett) Thank you, my Lord Chairman. We welcome the opportunity obviously to back up our written submission with oral views. My name is Tim Bennett and I am the Deputy President of the NFU.

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DR VERNON BARBER, MR TIM BENNETT,
MR BEN BOOT and MR ROBERT FIDDAMAN

[Continued]

[Chairman Contd]

On my right is Ben Boot, who is Chairman of our Biotechnology Working Group. Bob Fiddaman on my left, (and not Ian Gardiner, as the nameplate suggests), is also a member of that Working Group. On my right is Vernon Barber, who is a staff member of the NFU and scientist.

264. Thank you very much. Could I kick off and ask you this question: as and when the CAP is reformed, agriculture in this country should, in many sectors, be in a strong position to compete on world markets. In that context, should, in your view, British agriculture make full use of the technology of genetic modification, or do you think it should take a back seat and concentrate on the preservation and conservation of the countryside as it now is, with all its biodiversity?

(Mr Bennett) The short answer to that is that I do not think we have the choice. We are going to be exposed in terms of agriculture to a more competitive world, and the use of GM technology will be part of that more competitive world. I do not necessarily accept the premise in the question that by using GM technology, that you cannot preserve the countryside and biodiversity.

(Mr Boot) I think Tim has covered the point, my Lord, in saying that I do not think we have a choice. To suggest that the preservation of the countryside and biodiversity are the opposites of biotechnology, is a mis-statement of the position.

265. To concentrate for a moment on the competitive side, do you see it as being essential, for the future competitive survival of British agriculture, to embrace this technology?

(Mr Boot) I believe that is going to be essential. In order to remain competitive we are going to have to use biotechnology.

266. And is this feeling, would you say, widespread throughout British farmers? In America we see American farming galloping towards the full embrace of genetic modification over a wide range of crops. Now, I appreciate that the crops grown in this country are not the same, but would you anticipate that if the seeds became available in this country, that British farmers would go at the same speed and indeed the same direction as agriculture in the United States?

(Mr Boot) I think, my Lord, there are two things which worry us about biotechnology. One is the position of monitoring post release where we feel that more ought to be done to preserve the position, and to see that if anything goes wrong then we need to get that straightened out. The other is the possible rejection by consumers who, at the end of the day, are going to govern whether this technology is taken up.

Lord Jopling

267. May I begin by declaring an interest as a farmer and as a member of the NFU. My impression from your helpful paper was that you are concerned by the delays which occur in Europe. Could you tell us to what extent you think that delay might lead to further dominance by the United States' agriculture. Also, perhaps I can add the danger that if now we were

to try to involve ourselves in certain restrictions—for instance, if we had post agreement monitoring which turned up something that we did not like and we imposed a ban—then that could give rise to serious trade problems with the United States which, of course, we have had before.

(Mr Boot) I think Lord Jopling is correct in suggesting that we are concerned about the rate of uptake of technology. It is an unfortunate characteristic of the European system that if there is diversity of opinions from different countries' representatives, then they tend to fudge the issue and obscure the thing, which leads to slower decision making. The system in America seems to be much more conducive to more rapid decision making. Indeed, they are rather more adventurous in their approach to biotechnology than the European is traditionally. I do not know whether Dr Barber could give specific examples of where there has been a slowing down of the decision making process in Europe.

(Dr Barber) There are many examples of this but the Novel Foods Regulations is a obvious one, where it took about nine years to get to fruition. Almost as soon as it was in place it was outdated by events: imported soya and maize to Europe. The other is the EC Biotechnology Patenting Directive, which took nine years to get to fruition. It now looks likely to be passed and, indeed, will be in place in 2001. In the meantime, the standardisation of labelling throughout the EU is not in place. Therefore, those are two simple examples. What Europe is always doing is following after the events; not generating the regulations that are in place to lead events. So, for example, the Labelling Directive for soya maize has just been put into place and will come into action on 1 September. This is a very late reaction to the public concern about soya and maize. It should have been in place beforehand rather than after the event. This is just two or three simple examples.

(Mr Boot) If I may add, my Lord, if it is seen to be easier to get agreement on rules and regulations in America, then it tends to make biotechnology migrate to either Japan or the States rather than remaining native to Europe.

Chairman

268. Would you be concerned that if British agriculture was only able to follow on behind American agriculture in the use of this technology, that in years afterwards, even in decades afterwards, the position of British agriculture on world markets would be lost?

(Mr Bennett) Certainly the ability of British agriculture or European agriculture in this sense to compete on world markets would certainly be damaged. However, it goes beyond that. Our ability in our research and development in biotechnology would be lost because, by its very nature, you would have America and Asia leading the research and development into this subject. It would have a damaging effect to our research facilities as well.

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DR VERNON BARBER, MR TIM BENNETT,
MR BEN BOOT and MR ROBERT FIDDAMAN

[Continued]

Lord Gallacher

269. If certain Member States wish, in effect, to be GM free for growing or for sales, is there not a case for allowing them to be so, rather than to endure their attempts to create the rest of the EC in their image?

(*Mr Bennett*) We would certainly not impose views if Member States wanted to become GM free. But to be blunt about this, my Lord Chairman, I do not think it is practical.

270. Would you like to expand on the likely practicality?

(*Mr Bennett*) We operate within the single market, let alone a world trade mechanism. For example, just in animal feed alone, some countries would have to import some animal feed from America or Asia, which might have some genetic modification. It would be very difficult to say that it was GM free. So we come back to the fact that I question the ability for that to be practical. Obviously, if Member States wished to do so, we would certainly not impose it.

Chairman

271. Might it not be practical when it comes to a matter of growing? There are some who say that conditions vary considerably between different countries, and Member States should be able to impose different conditions on the ability to grow genetically modified crops. Do you see that as being feasible?

(*Mr Bennett*) If Member States wish to prevent GM crops being grown that is their decision. It certainly will not prevent that Member State from being GM free if it is available within the single market.

Lord Moran

272. Could you tell us how you think the wider issues are best taken into account in the process of regulation? You have called in your paper for an over-arching committee. Could you tell us what you think that would do, what its remit would be, and what it could do that ACRE and ACNFP do not already do?

(*Mr Boot*) The difficulty we find with the existing system is that ACRE and ACNFP are responsible to different Government departments. The creation of the Food Standards Agency as a single authority does actually give the opportunity to bring a more co-ordinated process into place. We foresee that would be an advantage. It does not essentially alter anything. The personnel involved on these committees do talk to one other but it would be helpful, we think, to have it more formally co-ordinated.

273. To which Government department do you think it should report?

(*Mr Boot*) It would probably be a combination of Health and Agriculture, in the same way as the Food Standards Agency is envisaged.

Chairman

274. The main concern about what is not fully covered under existing regulatory arrangements are longer-term environmental concerns. How do you see

these as being dealt with by the Food Standards Agency?

(*Mr Boot*) We would ask that governments should play a stronger and more specific role in post release monitoring because it is in that area that we feel that consumers deserve more comfort, more confidence. Especially in the early stages of biotechnological development, it is important that there is this assurance given by this greater confidence, so it is important that post release monitoring does go on. It is also important that this should be independent. At the moment, it is the responsibility of the company to actually pick up anything that goes wrong. We feel that is insufficiently independent.

Lord Redesdale

275. We had some evidence from Safeway which showed that their tomatoes, through being genetically modified, actually made it an easier crop to harvest and resulted in less waste when processed. What sort of modifications would you actually like to see as farmers?

(*Mr Fiddaman*) The modification we are always looking for is something that will improve the quality of what we are trying to produce. Certainly looking at some of the arable crops and the recent potential development of a better quality wheat, for example—which has been very difficult to do through the conventional breeding because it is a multi-factorial activity through the plant—the fact is that we have been able to identify the gene group that would increase the crop, which is something which the industry have been trying to achieve for a long time, because we know we can supply the product the consumer wants. It is that sort of development which we would obviously find very welcome. You mentioned the tomato situation. Yes, it has made it easier picking. The best thing is that it has been better quality and equally the price has been right for the consumer. These things very much concern people.

276. Do you find that scientists actually ask what you need, or do they come up with products which they think you will find useful?

(*Mr Fiddaman*) I think it is fair to say that the scientists are driving what is being produced, namely because they are identifying what is available. I would suggest that a number of things they are identifying is based on the industry indicating its preferred area for development, through the R&D discussions we have had with them on the various working groups.

(*Mr Boot*) The scientists are governed partly by what is easiest to modify. Herbicide tolerance is a characteristic which is generally covered by only one gene. It is easier to modify one gene biotechnology than a multiplicity of factors.

Lord Rathcavan

277. A lot of the development is commercially led, i.e. herbicide or pest-related. What do you feel about more unconnected developments, like frost-proof characteristics in potatoes, where there is not such a commercial link?

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(Mr Bennett) As we have already indicated, we feel so far that the debate has been generally headed by the scientists and what they can develop quicker and get to market very quickly. We, within the levy boards and the R&D groups, are actually getting through to the scientists on certain R&D work that we want done, and linking into it some of the concerns that my noble lord is indicating.

Lord Moran

278. A great deal of the debate and, indeed, the work of this Committee so far, has been dealing with crops and plants. But I wondered if you could tell us what your view is about the development of genetic engineering of animals and fish in agriculture in this country? What do you think are the immediate prospects for working in that field and are there risks which you think we ought to take into account?

(Mr Boot) I think, my Lord, that the issue of genetic modification in animals is a great deal more sensitive than in the case of plants. It is clear that people are a lot more wary of engaging in genetic modification in the case of animals. I think especially if it involves the transfer of human genes into animals, which is clearly possible, then people get very wary indeed unless it is for preventing terminal disease or death, and then it looks as if the human population changes its attitude to become more tolerant of genetic modification in animals. The whole area is, as I say, very much more sensitive. It is only if it is for the benefit of human health that there is likely to be much development in this area.

279. Has there been much progress in this country in work on animals or fish?

(Mr Boot) Could I ask Dr Barber, who can perhaps cover the developments that have been, in particular, at Edinburgh, through the sheep side particularly.

(Dr Barber) The Rosslin Institute is the world leader in this case, as you probably know. In their case they presently have alpha anti-trypsin, which is a chemical. This can be used for treating various respiratory problems, particularly cystic fibrosis, and that is in clinical trials at the moment. It looks as if it will become commercially available within the next two or three years. So alpha anti-trypsin is a chemical used for treating lung disorders and the Cystic Fibrosis Organisation have supported research in this area. It has fully supported this sort of the work. As Ben has said, it is quite common for people to look at this area quite differently in the animal areas, as far as human feelings are concerned. As far as other research is going, it is quite clear that biotechnology will be used in animal reproduction. The idea of cloning, for example, which is a bugbear view in some people's minds; however, it seems obvious to me in future years that this will be used as part of normal reproductive technology, much in the way that artificial insemination was used 50 years ago. Controversies were in place then. The other area might be progress in the animal/human use in the situation with regard to marker assisted breeding where there is no actual transgene put into the animal, but the selection from

particularly favourable characteristics for eating or other purposes are selected by that particular means. That seems to be an area where there is not likely to be very much controversy; where you might expect to have animals which will have improved characteristics which we, the public, might find, as a whole, more acceptable because there is not any transformation of genes put in or taken out from these particular animals. In other parts of the world there is a lot of work going on in other sorts of human uses. You have all probably seen the discussions about modified animals for transplant purposes, for example. This is an area of very active research at the moment. There is a moratorium in Britain on the use of animal organs to be used in humans because of the possible risk of viruses from these pigs, usually from the transplant donors to humans. It seems to me to be not a huge problem but there is certainly a worry there that there is a risk, so there are areas of that sort which are quite actively being researched.

280. The related problem is, I suppose, the use of transgenic crops; factories for producing pharmaceuticals.

(Dr Barber) That is correct. There are a number of ways of making pharmaceuticals. One is to use crops. One is to use cells. There may be cells which are deliberately cultivated for this purpose. The other is to use microbiological organisms.

281. If that is done, will that not expose birds and animals to ingesting all sorts of drugs?

(Dr Barber) Well, the crops you are talking about are only being used in test situations, very controlled areas, usually in greenhouses. It is not anywhere near commercialisation. Obviously when these things come up, (if they ever do), for commercialisation, the decision as to whether they should be grown or not will depend on the regulatory authorities. We are quite confident that the ones in the United Kingdom would make the right sort of decision in respect to those sorts of products.

Lord Jopling

282. But are you not concerned, in the whole of this field, that so far we have only just scratched the surface? There are many other things. I can give you examples: a nitrogen fixing wheat, and I can remember at MAFF going to buy pigs in China which had very high litter numbers. Our people were wanting to transfer their genes into European breeds. There are a whole raft of these things where we do not really yet understand all the possible applications. We have had a scare story, within the last few months, with regard to corn borers in maize, Swiss work which you are probably aware of. This shows there could be a whole raft of secondary effects or even a mistake in transferring a gene that, in fact, messes up adjoining genes. There is an area here where there are people who express great anxiety as to what we may be uncovering. Does this not cause you discomfort?

(Mr Boot) It would do, my Lord Chairman, if we were not convinced that the Advisory Committee on Novel Foods and Processes and the Advisory

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Committee on Releases into the Environment did not do a proper job. It would be complemented by our suggestion of further study of post release monitoring, which would provide extra assurance that the process was not going to get out of hand. I think we feel that the existing parts of the process are fine and could only be improved by that.

(*Mr Fiddaman*) I think it highlights the importance of being able to do early trials under constrained conditions, so that we are able to understand exactly the sort of questions you have been asking as to what can happen. If you can only do this on a small trial basis, unless you can trial it outside the greenhouse, which is an enclosed environment and which is not typical, then how are we going to be able to have the answers? The concern obviously of that is that unless we can have these trials done on a wider basis under controlled conditions, we will not get the answers; and we will not get the confident reply that everyone expects, including ourselves. Certainly there is no way that I, as a farmer, would want to grow a crop in which I was not confident.

Lord Willoughby de Broke

283. Are you concerned that with the increased use of genetically modified seeds, for example, that there will be fewer varieties of crops available? Are you worried what effect that could have on production in other countries?

(*Mr Fiddaman*) I do not think I am concerned about the reduction in the number of varieties. The current situation is that there are always more varieties that are being produced by the breeding companies than we currently have on offer. The difficulty is controlling the mechanisms by which they are mass-produced for industry. For example, if we are looking at specific advantages, take biodiversity. This is when the trial mechanism has a very broad basis to work from. We will look for various conditions according to particular commercial pressure. GM will only be added at a particular point in a particular grouping variety, but it does not mean that those other varieties are no longer available. So I cannot see it actually reducing the total variety of biodiversity because of that reason.

284. Surely, if farmers are seduced by the appeal of GM seeds and they become widespread, current varieties will fade out. You could be left with fewer varieties: this would magnify the problems of crop failure. If there was something wrong with those few varieties there would be danger and implications for countries like China and India.

(*Mr Fiddaman*) The fact is that if you are looking at a particular usage—I am thinking in terms of herbicide tolerance—if we were to see an introduction of a herbicide-tolerant feature in a group of varieties, the rest of the characteristics of those varieties will not change. What you are suggesting is that we would only have the availability of that particular herbicide tolerance. However, there are still enough breeding companies out there which breed for other reasons and that will not be the only source of, let us say, an oil

seed rape, particularly the development of that. The fact is that there is likely to be much genetic modification in the types of oil that each rape will carry, which will keep a very broad base of genetically modified varieties to allow that breeding to continue.

Lord Moran

285. I ought to declare an interest. My wife has a small hill farm in Wales with pedigree cattle. Does it worry you that transgenic crops could themselves transfer pollen to wild relatives, which then themselves become weeds?

(*Mr Boot*) Our position is, I think, as informers, that we are concerned to the extent that we think there ought to be a system of post release monitoring. The indications are that it is unlikely to occur to the extent that it is presented by those who fear that. So it is better to act against the possibility of that happening and by having a post release monitoring system. That is one of the main reasons for adopting that policy.

(*Dr Barber*) It would depend on the type of crop we are talking about. For example, the possibility of that happening with the oil seed rape, which you have obviously mentioned, is considerably higher. The studies which have been done on oil seed rape shows that it depends a bit on the weed species in the area. In France they have had positive results, as far as the crop is concerned, rather than the United Kingdom oil seed rape. So it depends on the environment to some degree.

Lord Grantchester

286. I declare an interest as a farmer in Cheshire and as a member of the NFU. I have two questions on the crops modified to be herbicide-tolerant. Are you concerned that a farmer may become dependent, with all the implications of this dependency, on a single supplier of seeds and herbicide? My second question is on consumer perception. It seems to me on this issue that the consumer has reservations because the technology is seen as benefiting the farmer rather than benefiting the consumer. Would you agree?

(*Mr Bennett*) On the question about whether we are concerned about being tied to a single supplier of seed or for herbicide, as an industry we would be concerned about the growth of multi-national companies, of very large powerful companies, as an industry. So the answer to that question is yes.

(*Mr Boot*) I think the benefits issue is an involved one, my Lord. It is one where we would expect benefit to work through the system. It may be that the introduction of a benefit is of primary benefit to a multi-national seed and chemical company, but unless it is a benefit to the grower through financial benefit, which he can pass on to a greater or lesser extent to the consumer, it will not get taken up. The benefit tends to spread out through the chain rather than being restricted to one particular sector. To say that all the benefit is going to accrue to the multi-national chemical or seed company is an over-simplification of the position.

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Chairman

287. Could I come back to Mr Bennett's answer, where you say that you are concerned about the growth of the big multi-national companies. Why is that? Is that because you think it is going to lead you to a situation where there is an insufficient degree of competition between those companies in the industry?

(Mr Bennett) Certainly we would not want there to be dominant forces, even though this might give some choice within those companies. We think competition is a good thing.

(Mr Boot) I think their emphasis tends to be on the good of that company rather than perhaps the good of the farmer or the grower.

Lord Gallacher

288. Could I ask, apropos multi-national companies, whether the NFU is at all concerned in this context about the remoteness of the shareholder from control of the multi-national companies which, in certain circumstances, could be dominated by scientists or those who are concerned only to produce a good trading result?

(Mr Boot) Men in white coats and things like that.

289. Precisely.

(Mr Boot) Yes, I think we are. I will ask Dr Barber to cover the steps that we have taken in order to preserve farmer privilege in Europe, which have been to some extent successful; but the whole area is one where we are, like everybody else, frightened of the potential development of power by multi-national companies.

(Dr Barber) One of the advantages in the new Patenting Directive is that it does contain articles in this which do protect farmer privilege. So, for example, there is an ability to save seed in that Directive, which was a very important feature as far as we were concerned. In the same way that the use of animals is protected, so breeding is protected in this Directive. One of the problems for us rather than for America are the very exclusive contracts that limit the farmer to obtaining the second year seed from the same original supplier. This would not be legal under the EC Directive. Some of those contracts, which have been highly criticised in the farming press and elsewhere, are very restrictive. I suspect they would not be found to be acceptable to most British farmers. So there are protections there built into the legal system which we are very pleased to see; mainly put in by the efforts of our representatives in the European Union and also by the European Farming and Agricultural Co-operative Union. They have made efforts for that to be included and it has been.

Chairman

290. Does the terminator seed concern you? Crops which do not reproduce, and so farmers have to go back to the company to buy all their seed for the next year.

(Dr Barber) There are several technologies to try to avoid the transgene getting out into the general weed population or to the other crop population. That

is just one of the technologies. Another technology is to incorporate this into the chloroplast of the plant. Terminator seeds is one way of doing this.

291. What we are really asking is, would you be concerned by having to buy your seed from the supplier the next year?

(Dr Barber) That would be a concern. In particular, the developing countries are a bit nervous as this could be seen as a way of taking over their farming industry. Personally, I believe that seeds will be too expensive—for example, with the terminator—for most of those countries, for farmers to afford this. I have my suspicion that it is not a very important technology in their regions. It may be in our regions but it is not in the undeveloped areas, I suspect.

Lord Grantchester

292. May I follow up on that, please? Have you been in contact with your members undertaking trials regarding the rising incidence of eco-terrorism and would you support, as I have heard others call for, for these trial areas to be kept secret while the results are being monitored?

(Mr Bennett) We are obviously concerned about trial plots being destroyed because the basis of what we are asking for is good trial work, good post release monitoring, and if we do not have good trial work undertaken and it is destroyed this causes some difficulties. We accept that we have to release a certain amount of information to the public in terms of what trial work is taking place. We think it is unwise actually to give the locality. We would like to see the actual locality taken away from the public information so that we can make sure that we have good, sound, robust R&D work taking place. We accept that there has got to be some sort of public information on what sort of trial work is taking place.

(Mr Boot) The key to the adoption and acceptance of the technology is good information. Everything seems to indicate that once people become more familiar with the technology because of openness of information and good communication, that they are more likely to accept or take a view that is based on science rather than supposition. It is important, I think, in the development or the introduction of biotechnology in the early stages, that the public do base their views on science rather than supposition. You get yourself in an unfortunate situation if it is all based on a view that God should be responsible for it, or whatever.

Lord Gisborough

293. I should also declare an interest as a farmer. Is it practical to require segregation of crops while they are being grown and stored in agriculture? How would this be consistent with the traditional freedom of farmers to grow the crops of their choice?

(Mr Bennett) First of all, it is practical. In fact, it has already been undertaken by a lot of our members who grow seed crops. This is the normal procedure that they undertake. Certainly, in terms of segregation of crops while being grown and certainly stored on a

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farm, that is perfectly practical. In terms of the freedom of farmers to grow crops of their choice...

(*Mr Fiddaman*) I think the point, my Lord, on having a choice and being able to segregate is the fact that you are able to make a decision. I am a seed grower. I grow crops which require discussion with my neighbour. Under the conventional growing of them you need to be able to keep a pollen distance—with pulses, for example, they are open flowering. My neighbour, who is growing a crop right next to mine, will effectively be able to stop me growing a seed crop. By discussing with my neighbour I am more able to grow the same sort so that I do not have that barrier problem, or I move the crop myself, or he might even change his cropping programme, or her cropping programme, so there is not a problem of an effect. The segregation of the crop is certainly very easy on a farm. As far as post release movement is concerned, it is entirely due to the strength of middle and end users that they will wish to see that segregation, according to the direction that they are provided with, to produce certain crops in due course. Where there are changes, for instance, within a crop which is herbicide-tolerant, this does not matter because it is not going into the oil. The oil that is produced at the end of the day is no different from that oil produced by the genetically modified variety.

Lord Redesdale

294. In the case of an organic farmer, where someone is growing a GM crop very close to his, what is the convention there? If, from what he was saying, he seemed to have no choice and he was going to lose his organic status.

(*Mr Fiddaman*) I am aware of his concern. Obviously the concern again is a matter of distance. It is recognising what distance becomes, if you like, the contaminant barrier. Certainly within the seed growing there are recognised distances over which these pollens will not effectively travel to cause a problem. Certainly our recommendation would be that those sorts of distances would be the sustainable answer.

295. But there will be no organic farmer who can actually enforce a buffer zone round his own fields other than on his own land?

(*Mr Fiddaman*) In the sense that if it is a crop which is known to be genetically modified, my reaction as a conventional grower would be to see that there is a barrier of another crop between. Similarly, I have to confer with my neighbour. Certainly we would have no difficulty in recommending that those wishing to go into genetic engineering in the early period should certainly discuss with their neighbours their intention, so that they are aware of what is happening rather than the fact that there is any particular risk. That is very important for those organic farmers, and certainly those who are farming round organic farmers will be aware of their existence.

Chairman

296. So is segregation something that you consider, for the most part, should be and will be market-driven and market-led rather than be required by statute?

(*Mr Fiddaman*) I would certainly see that being the end result. In the first instance, it is logical for consumer confidence that we offer it as an opportunity. I think, at the end of day, that if there is seen to be no problem with the end product we will eventually see segregation, as there is with the other varieties now within the oil seed sector. We have the segregation of the *Hero* that is maintained throughout the sector. I see no problem in maintaining that in other areas.

(*Mr Boot*) Unfortunately, this whole business of segregation is somewhat broken down because of the refusal of the American growers to segregate or label soya as being genetically modified.

Baroness Young of Old Scone

297. I would like to pick up the references to the American line on segregation. You may not be able to answer this one but certainly in some of the previous evidence we have had there has been a suggestion that some degree of segregation is now beginning in America, partly because of the lack of ability to monitor the impact of genetic modification if there are not control areas, and also because of the concerns about gene-creep into other species and the impacts on beneficial insects as well as non-beneficial insects. I wonder whether I could ask you your thoughts on that, and also on the differences in the system which I think is used for approving GM crops in the United States. In many cases the environmental benefits from the growing of the crop emerge from major transfers to the no-till system rather than a system of tillage. The question really is whether you see both of these factors, the segregation system and the no-till system, as being useful or likely in this country.

(*Dr Barber*) The situation in America is very, very particular but one notable thing about it is that even though one company in the United Kingdom is attempting to obtain non-GM soya, they have said they cannot do it essentially. This is Iceland. They have said that they can obtain it from a non-GM source, but this quite different from saying that they can obtain non-GM soya. What happens in transfer of material from the actual fields in the United States to the manufacturing processes in the United Kingdom is that there is always a risk at every level of procedure of some soya beans getting mixed, some GM with a non-GM source. So it might become impossible. It may already be impossible to guarantee a complete non-GM source to a manufacturer in the United Kingdom. So there is a problem there. What the Austrians have done is have an organic status which recognises what they call point one per cent adulteration in their non-GM material. A small amount is allowed but it is still organic in their definition. My suspicion is that something of that sort will be required in the future because it will be impossible to guarantee completely non-GM material. It does not matter how

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hard you try, it might well be impossible. The tillage point I will pass on to my farming friends.

(*Mr Fiddaman*) Certainly, as you rightly say, the Americans have shown the advantage of the pesticide tolerance factor in the fact that you can go in and plant a seed and destroy the old cover crop that was there protecting the soil. You have got to remember this is on the back of a water shortage basis and that is one of the reasons for looking at no till. There is certainly a move towards no tilling in United Kingdom agriculture in terms of cost reduction. How much of this will be reliant on chemical reaction? I would suggest not. The benefits of being able to use herbicide tolerance to modify your chemical practice are in the fact that it is a more benign usage than some of other chemicals that we might be using on a conventional crop in those same circumstances.

Chairman

298. Could I ask you about crop rotation, which relates to no tillage. I presume with no tillage there is no crop rotation. Generally, do you see genetic modification affecting crop rotation if it came in widely in this country and would that concern you?

(*Mr Fiddaman*) In itself there is no reason why it should actually affect crop rotation because I think a lot of it would be done on good farming practice. In other words, we already see the advantage of having a break crop in the production of a first wheat crop because it actually gives benefits to the first wheat crop. The change in that area might happen whereby if they are able to protect the crop against the particular organism that affects continual cereal growing then those soils that are particularly good at cereal growing, wheat growing would probably return to it. However, there is a lot of people today doing continuous wheat on those sorts of land. In general terms I cannot see it making a big difference to a rotation. I could actually see a positive advantage, particularly with something like the herbicide tolerances that are being put into the oil seed rape because some of the difficulties within the cereal growing cycle is that we cannot knock out some of the competitive graminiae weeds, which things like glufosinate are very good at removing and being able to take them out late in a rape crop and therefore stopping a seed deposit during that part of the rotation would reduce pressure on other parts of the cycle. I can see those actually being used as a positive benefit to the rotation.

Lord Rathcavan

299. I would like to ask a question which relates to the earlier one on useful modifications. Most of the development of GMOs is in crops and it gets, as far as the consumer is concerned, diluted in the end product to a great degree. As you said earlier in your evidence, so much depends on the acceptance by the consumer at the end of the day. As far as we know there is only one pure GM item on the market which is this tomato paste which is available and marketed as a 100 per cent genetically modified product. Do you think that to get greater consumer acceptance you should encourage

more GM fruits and vegetable products—and maybe cereals—to get pure GM products on the market. The consumer is undoubtedly confused at the moment when a very small part of soya or maybe maize in the future is involved.

(*Mr Boot*) Yes, I think you are right. There is another product and that was the cheese made with the aid of chymosin rather than rennet extracted from calves stomachs which may be perceived to be an unfortunate business as far as the calf is concerned. In both cases I think it is fear of the unknown is the real enemy and it becomes possible for the consumer to be thoroughly familiar with a GM product where it is labelled as such and available side by side. The indications with the GM cheese were that it actually out-sold in a side-by-side trial traditional cheese, if you want to call it that. I am sure you are right, my Lord, that it is a much better way to familiarise the consumer where you have labelling, you have segregation and it is possible to draw a distinction between a GM product and a non-GM product.

300. Where do you see further development in unique GM products?

(*Mr Boot*) This is where it becomes very difficult because of the position on soya for example, soya particularly, because soya is included in about 1,000 products on supermarket shelves. It is very very widely used and no distinction is possible.

301. Would you like to see the development of a GM strawberry, a GM cauliflower or potato chip?

(*Mr Boot*) It would clearly be possible if it was for a particular reason. You mentioned the strawberry and of course that brings up the question of irradiation which has been rejected in effect by the consumer and there is theoretically no irradiated produce available in this country except for herbs like marjoram.

Chairman

302. On the superweed problem I think you stated your preferred solution. Could we have your view on the solution of making the plant male sterile or female as a solution to out-crossing and therefore risking the reduction of the superweed. Would this bring to an end the farmers' practice of reserving seed and, if so, would that concern you?

(*Dr Barber*) That is one option. As I point out, there are a number of ways of trying to ensure that out-crossing does not occur. That is just one possible way. The other way is transgene chloroplasts and another way is to use terminator genes. We do not yet know what process will be the acceptable one. It is impossible to say at this stage. The chloroplast one, for example, you can put very many more transgenes into the chloroplast than you can put into the normal genome. That might be one of the ways. We do not know at this stage.

Baroness Young of Old Scone

303. In your evidence you have called for post-release monitoring. You said that it should be conducted either directly by government or under

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contract from the government. Can you expand and say what should be monitored, how the monitoring should be conducted, what the role of the farmer would be in the monitoring and who would pay for the monitoring?

(Mr Boot) My Lord Chairman, to what extent should farmers be involved? They are extra eyes and ears. They are part of the monitoring process. If government have a responsibility in this area it need not necessarily involve them running extra trials themselves. They can then initiate trials through the grower or the product presenter. It would seem to me we should bring them in as part of a chain with a responsibility for taking up any case that was put to it by either the user, any outside observer, an advisory service, the farmer or indeed the company itself, if it wishes to bring to the notice of government some peculiarity or some development which it felt to be potentially undesirable.

304. Would you see this as being a statutory set of things that were required to be monitored or would you see this as a purely voluntary process?

(Mr Boot) I think that an element of statutory enforcement is essential because there is a tendency for it not to get done if the company had an interest in not revealing that some undesirable development was occurring, or at least the consumer might suspect that.

305. Could we perhaps get you to expand a bit on what it is that you would see requiring to be monitored.

(Mr Boot) If there is a development of a superweed, for example, or the passing of some of the genetically modified characteristics from one plant to another, if that becomes sufficiently threatening then it may warrant trying to put the process into reverse if you can. The sooner you start to do that, the more likely you are to be successful.

306. Do you think there is a case for monitoring the actual agricultural practices of the farms on which these products were being used in terms of both herbicide and pesticide application for example, or in terms of rotation which has already been raised?

(Mr Boot) I think there is definitely a case for allowing the farmer to have a role in the monitoring because he is closest to what is occurring in the fields or on the farm.

Chairman

307. It would take the form of conditions, would it, attached to the permit given to grow?

(Mr Boot) Yes.

308. Would the primary responsibility and liability lie with the company who has provided the seed or with the farmer who is growing?

(Mr Boot) It does now, my Lord I understand, but perhaps Dr Barber could cover the position now. It is a question of whether government has a place. The responsibility of ACRE and ACNFP for example is to try and anticipate the existence of any such problems post release. They have to do it by trying to forecast rather than by actually observing and it seems to us to

be necessary to actually observe what does happen in practice post release to have a more secure system. Could I ask if Dr Barber would answer.

(Dr Barber) If I could add one or two comments. The new revision suggested for the EC Directive 90/220 does recommend a seven-year monitoring period. It may well become a statutory requirement via the European regulations if they pass through. So far as the monitoring process itself is concerned, one can envisage a whole range of possible studies to be undertaken. As an ex-research scientist I can envisage lots of them, for example, simply looking at the changes that may occur in the micro-organisms in soil or changes that might occur in the insect or other populations in the areas where the various crops have been grown as the sorts of things that will be monitored at least in the early stages. It may well be the case that the changes are relatively minor and in future it would not be necessary to make those checks because monitoring processes would carry it through. At the beginning I think it is important that we see what happens in real life as opposed to what happens in a test situation or what we think might happen from theoretical studies. So you can envisage a whole raft of changes.

309. There are some respected organisations that have called for a moratorium on all genetic modification on the grounds that not yet enough is known about the long-term effects. Do you see post-release monitoring as being an alternative procedure to a moratorium, a route you would rather go down whereby conditions are attached to permission to release and if the outcome is not as desirable as hoped then possibly the permission to grow would be withdrawn?

(Dr Barber) The suggested changes in the EC regulations do actually have a withdrawal capability after monitoring or even in the middle of the monitoring period so that has been anticipated by the European regulators. As far as the moratorium is concerned the Government have said quite clearly that is not legal in the European Community so whether we like it or not it is not legally possible. As far as the alternatives are concerned clearly nothing should be authorised for growing in commercial quantities without it being considered to be safe. We do not believe the United Kingdom regulatory authorities have actually made such an authorisation. Clearly if there is a doubt about what environmental effects there might be these must be investigated by test growing activities. Unfortunately, as we discussed earlier on, this year there have been 21 destructions of crops out of about 300 test sites. It is becoming more and more difficult to carry out these sorts of activities.

(Mr Bennett) On post-release monitoring we actually feel this is an integral part of reassuring the consumer and so on that basis we feel if the consumer is going to feel assured about the development of this technology some sort of statutory mechanism needs to be in place rather than voluntary.

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DR VERNON BARBER, MR TIM BENNETT,
MR BEN BOOT and MR ROBERT FIDDAMAN

[Continued]

Baroness Young of Old Scone

310. Can I just follow up the last point which is who you would see being responsible for that within the framework set by Government and who would pay for it?

(Mr Bennett) We felt it should go to the Food Standards Agency to say that they take a view. In terms of monitoring the actual crop in terms of the farmer that is part of his normal procedure. If it is a public health issue then obviously the Government should undertake some of the cost.

Lord Jopling

311. In your paper you advocate very detailed record-keeping and traceability for GM crops. Do you think that that is a practical suggestion right across Europe or indeed for imports which is a much wider problem than the situation within the European Community?

(Mr Bennett) Well, my Lord, as you are probably aware, the NFU has been at the forefront of the development of farm assurance schemes where we actually can in terms of the United Kingdom certainly deliver the full record-keeping and traceability and even independent verification in the future in this country. Obviously, across Europe it depends on how they develop their own schemes but in terms of imports we could not possibly comment. At the moment we would doubt they would have that capability. We intend in terms of our own market to make sure we can deliver full record-keeping and traceability.

312. I have no doubt about that. I am sure you all do, as I do, have bitter memories of things being agreed in the Council of Ministers which then become totally ignored in other Member States. I have no doubt that we can do it here but do you think it is a practical suggestion in terms of the whole of the European Community and indeed on a wider basis or is it rather pie in the sky?

(Mr Bennett) I have some doubts that we will be able to be reassured about the full traceability of imports, my Lord.

313. And within the European Community, is it seriously practical or is it just wishful thinking?

(Mr Bennett) If it is practical, as we see it, within the United Kingdom then it is certainly practical within Europe. Whether they will do it there I do not know I am in a position to answer that question.

(Mr Boot) I think, my Lord, there has been a move towards much greater traceability and accountability for one's produce which is accelerating and I think we have to take account of this. Whilst we have our doubts as to how effectively this might be pursued in foreign parts, that I think probably is no more than chauvinism often.

Lord Moran

314. If something goes wrong with a genetically modified crop either in relation to human health or to the environment, who is going to be responsible? Should farmers be liable?

(Mr Boot) My Lord, if the genie gets out of the bottle who is liable? We fear that the multi-national company will put the corporate lawyers on to the issue to the point that they make sure that it is not their fault, it is some poor old farmer, and I think that our concern would be to protect the farmers' position in that scenario. It is not an issue that has been decided at all yet and I suppose it is going to be interesting when we get the first legal cases that are taken up on this. If something does go wrong who will be held to blame? I share the concern about the question.

315. I am sure you are right in the fears you express but does this not mean that you ought to be thinking about it very seriously now to protect the farmer? Because somebody has got to be responsible if there is damage.

(Mr Boot) We have thought of the question, my Lord, but I am not sure we have come up with the answer yet.

Lord Jopling

316. You have thought of the problem but has your research discovered whether most farmers' general liability insurance covers an eventuality of this sort?

(Mr Boot) We are told that it does.

317. It does?

(Mr Boot) We are told so.

(Dr Barber) Could I add a rider to that. Some of the contracts that have been signed in the United States have attempted to pass the liability directly back to the farmer and to his or her descendants and that sort of contract I personally suspect—if I can get agreement on the table—we would find unacceptable for United Kingdom farming. Obviously when these contracts are made available to farmers then the legal department will look at them and advise our members appropriately.

Lord Gallacher

318. Are you aware of the Community's proposal to withdraw relief which you now enjoy in respect of primary products, and the liability indeed therefor?

(Mr Bennett) Yes.

319. Thank you. The evidence we have taken from other witnesses leads us to a position in which we are aware that the public perception is that GM foods are not perhaps as safe as they might be and are therefore not as attractive as they might be to consumers, with the notable current exceptions of tomatoes and cheese, which have been mentioned. It has been put to us that this is partly due to the BSE scare and other food scares. Do you think anything can be done to address this problem and, if so, where do you think the responsibility for doing that should lie?

(Mr Boot) I think that the answer to the thing, as I think we have indicated both in the papers and in our oral evidence, is openness of information and continuous availability. In considering what part we might play in this we felt that our best opportunity is contacts within the industry and with the growers and

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DR VERNON BARBER, MR TIM BENNETT,
MR BEN BOOT and MR ROBERT FIDDAMAN

[Continued

[Lord Gallacher *Contd*]

farmers rather than with the consumers and we felt that the best means of contact with the consumers has been via the supermarkets where they are trusted by the consumer for the most part and they have a regularity of contact and that makes it important that we maintain contact with the Institute of Gross Distribution, for example, and with the individual supermarket companies, but we have tended not to take up the challenge of contacting the consumers to any great extent.

Lord Gallacher] Thank you.

Lord Willoughby de Broke

320. Could I just follow up on that? Your earlier suggestion for an over-arching committee we have already heard about. Would you recommend including consumer representatives and organisations on that over-arching committee?

(Mr Boot) Yes.

Lord Moran

321. I am sure that what you say about the supermarkets is absolutely right. Some of them have told us that they attach enormous importance to the question of labelling and indeed have done this with great success on tomato paste. Do you think that this work has been undermined by the refusal of the American growers to segregate soya and that that torpedoes the whole affair?

(Mr Boot) We would say so, yes.

Chairman

322. As far as supermarkets are concerned are they putting any demands, or are they likely to put any demands, on your members as far as genetic modification is concerned?

(Mr Bennett) So far the only demand that we have identified in certain cases is the animal feedstuffs and the sourcing of animal feedstuffs, for example for soya which obviously then gets into the chain. That so far is the only problem we have identified.

323. Thank you very much. That brings us to the end of the substantive questions we had to put to you. We are very grateful indeed that you should have come with a very full team and given us very useful evidence. I hope, Mr Bennett, you will not take personally the question that I would now like to ask. Often in the past when you have had evidence sessions before the Committee the former President of the NFU came and gave evidence to us. Is it significant that your President has not appeared before us today? Does it indicate a lack of enthusiasm on the part of the NFU towards genetic modification or a lack of readiness on behalf of the NFU to take a position on the subject?

(Mr Bennett) My Lord Chairman, if I can apologise for my President. Four times a year the Council of the Union (which is the supreme body of the NFU) meets and it happens to be today that that Council meets. As the President is the Chairman of that Council it is obviously important he be there. On top of that as Deputy President my particular remit is biotechnology and research and development. That is why I have led the NFU team.

Chairman] Thank you very much. That is very reassuring. Thank you very much indeed.

WEDNESDAY 1 JULY 1998

Present:

Gallacher, L.	Redesdale, L.
Jopling, L.	Wade of Chorlton, L.
Rathcavan, L.	
Reay, L. (Chairman)	Clanwilliam, E.

Memorandum by Monsanto Services International S.A./N.V.

MONSANTO EXPERIENCE

1. Monsanto has extensive experience in developing genetically modified crops around the world. Since 1996 we have commercialised 10 products in the United States, Argentina, Canada, Japan, Europe, Australia and Mexico and have conducted several thousand field tests with genetically modified plants in many countries around the world since 1986. Monsanto has been actively involved in European and international discussions on the levels of safety assessment and regulation for genetically modified plants, including discussions sponsored by the OECD, WHO/FAO and the TABD (Transatlantic Business Dialogue).

2. Monsanto recognises the importance of well administered regulation, not only to ensure adequate levels of protection for human health and the environment, but also to provide public confidence in approvals and the authorities which issue them.

3. Monsanto believes that the regulation of genetically modified plants should: be based on scientific evaluation to ensure objectivity and consistency; be timely and predictable, to accommodate investment planning; be internationally consistent to ensure competitiveness; and be appropriate to the level of risk.

4. The following evidence will apply these criteria to the existing and proposed EU regulation of genetically modified plants, and where appropriate, contrast the situation in the EU with that in other world areas.

THE APPROPRIATENESS AND EFFICACY OF THE CURRENT REGULATIONS AT EUROPEAN UNION LEVEL

(a) *Research*

5. The EU directives 90/219/EEC and 90/220/EEC part B were established in the 1980s to regulate the research and development of genetically modified plants under contained conditions and unconfined conditions, respectively. National regulations were in force in some EU countries well before the implementation of the EU directives. After 12 years of research and more than 100 field releases in the EU, to our knowledge, there have been no reports of environmental damage or injury to human health. It must be concluded that the present safeguards are entirely adequate from these perspectives. The introduction of simplified procedures for certain categories of GM plants in 1994¹ allowed for reduced administrative procedures, whilst at the same time maintaining adequate safety precautions.

6. The current regulations are allowing research and development to proceed in most Member States, although a number of important changes are desirable to reduce the administrative burdens, encourage academic research, and to accelerate product commercialization. Improvements could be brought by: regulating research and development within vertical product regulations e.g., variety registration procedures and further simplification of the administrative procedures for identified "low-risk" GMP's particularly where experience has been obtained. This could be done via a "notification" procedure; introducing the possibility for simple multi-state authorisations to avoid the duplication of the paperwork and resources currently necessary to conduct field trials in different Member States.

(b) *release into the environment*

7. The regulation covering release into the environment includes the approval to commercialize GMP's under Part C of the Directive 90/220/EEC. The information necessary for safety assessments is described in detail in Annex IIB of the Directive.

8. The functioning of the directive has many serious shortcomings. These are evidenced by: The Commission's report on the functioning of the Directive since its adoption²; the number of products approved compared to other world areas with comparable levels of industrial activity and the time required for these product approvals (see Attachment 1, last updated 1/97).

9. Industry representative organisations, including EuropaBio and GIBiP, have previously documented their concerns about the current 90/220 directive, as well as the proposed revisions.

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[Continued

10. The underlying causes of the major deficiencies of the current directive have varied over time, but have included:

11. *Lack of clarity* of the scope of the directive and overlap with other legislation (such as Directive 91/414 concerned with the authorisation of plant protection products). This has led to confusion over the information to be provided by applicants.

12. *Failure of the standard 5-month procedure to operate* as foreseen. All but one of the 25 EU marketing applications have raised objections from at least one Member State. This has resulted from the inherent lack of clarity in the scope of the Directive, as well as the inclusion by Member States of objections based on criteria outside of the scope of the Directive (e.g. labelling, insect resistance management, herbicide use). The result has been that the predictability of the process is highly uncertain, thus leading to a much greater level of speculation on investment decisions than in other parts of the world.

13. The *comitology procedure* foreseen to resolve differences between Member States *has not functioned*. This is attributable to differences in Member States perceptions of risk and considerations of non-scientific criteria, making it difficult to find the necessary Member State support for proposed Commission decisions. The result has been regulatory uncertainty, and undermining of public confidence in the regulatory system.

14. *Lack of specific time frames for all steps in the process*, from Member States review (in some, but not all Member States), the Commission proposal for a decision, and the time for rapporteur country approval. This has led to unacceptable uncertainty in determining the return on investment in decision making.

(c) *Novel foods and labelling*

18. The Novel Food regulation⁴ has been in force since May 1997 and both industry and the regulatory authorities have had little time to develop experience with its operation. However, the issues raised during its drafting continue to be areas of concern. The principal so far identified concerns are:

- (i) (i) *Lack of a clear definition of "substantial equivalence"*. The procedure for the regulatory clearance of products is determined by whether products are substantially equivalent or not. Member States and the Commission have not formally agreed on a uniform definition, such as that developed by FAO/WHO and OECD.^{5 6 7} This is resulting in major uncertainty over expected approval timelines; and
- (ii) *Lack of a clear definition of "equivalence"*. "Equivalence" has yet to be fully defined because of the lack of uniform Community standards for the techniques to be employed and the acceptable sensitivity limits. Products which are no longer equivalent must be labelled as being genetically modified, in many cases for information, rather than for health and safety purposes.

19. As many of the products concerned by the Novel Foods Regulations are present in international trade there must be consistency with international rules and obligations to avoid trade disputes in food and agriculture products. Labelling obligations for information, rather than for scientific reasons, also risks creating difficulties in trade.

20. A more detailed review of the functioning of the Novel Food regulation will be appropriate once greater experience has been gained with the regulation.

(d) *Other regulatory considerations-variety registration*

21. The existing plant variety registration legislation does not distinguish between GM varieties and non-GM varieties. However legislation is in development which would allow for a transfer of the environmental and human health safety assessments from Directive 90/220/EEC and the Novel Food regulation into variety registration procedures. Notwithstanding these future changes, some Member States are using national variety registration procedures to add further conditions to the marketing of GM varieties. These conditions are, in some respects, contrary to Community (90/220/EEC) decisions, are not science-based and are an additional burden to industry, which decreases the competitiveness of European agriculture without providing additional safeguards.

(e) *Current trends and future developments*

22. *Approval timelines*: It was to be hoped that the functioning of the EU regulatory process would improve over time, as familiarity with the technology, product applications and safety assessments advanced. This has turned out not to be the case. Despite overwhelming evidence of the benefits of products commercialized in other world areas (James, 1997; Attachment 5) [not printed] and the lack of any demonstrated negative effects on the environment or human health, product approvals are regularly delayed beyond reasonable time limits. These delays are becoming longer rather than shorter. Failure of the Member States to reach scientific consensus

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[Continued

on all but one of the marketing applications (a carnation with altered flower colour) has contributed to these increasing delays. It is to be hoped that the recent introduction into the 90/220 process of reviews by the Commission's Scientific Committees will be a positive step towards a more science-based review and improve the overall functioning of the 90/220 process.

23. *Data requirements:* A further development which is contributing to the uncertainty in the regulatory process are the continual changes in the interpretation of the data requirements for safety assessments. Data requirements are outlined in Annex IIb of the Directive 90/220/EEC, but details are not provided. In the EU 90/220 process, a total of 16 scientific safety assessments are conducted on each product (one by each Member State and one by the Commission's Scientific Committees). The result has been bureaucratic difficulties in resolving increasingly divergent views on the most appropriate safety data set, and usually a requirement for applicants to respond to the combined data set. This has led to unanticipated delays and discrepancies between the European and international data requirements.

THE APPROPRIATENESS AND EFFICACY OF THE CURRENT REGULATIONS AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

24. An assessment of the operation of the current regulations at the UK or any Member State level cannot be easily distinguished from the operation at the European Union level. Many of the problems with the operation of the European Union regulation of biotechnology products stem from difficulties at the Member State level such as delays caused by uncertainties over eventual Member States decisions when drafting Commission decisions in preparation for referral to Member States for qualified majority voting.

25. Problems at the Member State level have been caused by various factors:

26. The original concept whereby other Member States would generally accept the rapporteur Member State's review throughout the Community has not functioned. All products must effectively undergo complete reviews in all Member States. It should be considered whether this current process should not be replaced by a Community-wide process such as a Standing Committee decision, as is the case in other areas of regulation, such as the approval of Plant Protection products.

27. Member State reviews usually involve consultation with several Ministries. In some cases this had led to conflicting scientific conclusions (for example between ACRE and ACNFP in the UK). These conflicts can only be avoided by strict adherence to well defined scientific criteria.

28. The introduction of local political factors, such as the timing of elections, or consideration of non-scientific factors, outside of the scope of the regulations, have often led to objections which contribute to the undermining of public confidence in the regulatory process.

29. Delays in formal approvals have also resulted from rapporteur delays in completing the approval process once the decision has been published in the European Official Journal, in some cases for as long as 12 months. Products may not be marketed until the rapporteur country approval ("consent") is issued.

THE MOST APPROPRIATE JURISDICTIONS (INCLUDING INTERNATIONAL REGULATION AND HARMONISATION) FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

30. International harmonisation of the regulation of GM crops is one of the major challenges facing the industry and the European Union. The EU and the United States are the world's two leading trading partners, and differences in the regulation of GM crops has already led to trade tensions arising from the following:

31. *Differences in the fundamental approach to the regulation of GM crops.* The "process-based" approach to the regulation of GM crops in Europe has often been contrasted with the "product-based" approach in other world areas.

32. There are *no separated and gradated "risk categories"* for marketing applications. Products approved for import into the EU for processing purposes only are subject to the same procedures and risk analyses as products destined for wide-scale planting in Europe.

33. Excessive bureaucracy and lack of time limits on Member State/Commission interaction, means that the *time for product approvals is considerably longer in Europe*, compared to other world areas, including the United States, Canada and Japan.

34. *The unpredictability of the process* resulting from various factors, including lack of clarity in the scope of the regulation, lack of transparency and predictability in the procedures to be followed and failure of Member States to comply with the directive.

35. *The regulation of products in the EU which are not regulated ex-EU*, such as varieties developed by hybridising previously approved genetically modified varieties.

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[Continued]

36. *Trends towards differing data requirements.* Despite general agreement to date on the appropriate information necessary to support product safety assessments, there are widening gaps between the EU risk assessments and those in other world areas. For example, some EU Member States are requesting that animal feeding studies be routinely included in safety assessments, contrary to OECD recommendations.

37. The EU requirement to *label for process*, without any safety or other scientific basis, risks creating barriers to the international trade in foodstuffs.

38. The result of these differences, particularly the delays and the lack of predictability of the EU process has been interference with global trade in agriculture and food products. There is clearly a need for a more harmonised international approach to the regulation of GM crops.

THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION

39. The style and operation of the regulatory system as it affects biotechnology in agriculture impacts the whole food chain from efficiency and cost of food production through to access to higher quality and more nutritious food products. Further, the Commission's 1994 White Paper on biotechnology, growth and competitiveness and employment reports that "in future the entire system of related provisions on biotechnology must ensure that the [regulatory] controls are always in proportion to the risks which exist, the need to build up confidence in the public and to the competitive development of the industry, whilst at the same time human health and the environment must be protected".

40. Europe's agri-food industry possesses the potential for innovation which combines cutting edge technology with responsible and sustainable use of resources and Europe can have the same strong record in innovation and a leadership role in agri-biotechnology as that which already exists in several other key industries, including communications technology, pharmaceutical research and development and environmental technology: this is provided the regulatory systems which govern the introduction of the technology are effective in practice, have the general confidence and trust of the public and correctly weigh the benefits against any possible risk.

POTENTIAL BENEFITS

41. The many identified benefits of agri-biotechnology include:

42. An innovative and sustainable agri-food sector matching consumer needs and the demands of an expanding modern economy. *Strengthening of the agriculture and rural community as a responsible and important partner in Europe's growth and development. Better land and resource management to help preserve natural resources and ecosystems. Access to food crops with improved nutritional value resulting in a healthier society. Access to crops with built-in protection from insect pests and resistance to viral and fungal diseases resulting in new and more effective options for the farmer. Access to crops with enhanced temperature, salinity and drought tolerance which make better use of available land. Diagnostic agents for plant and animal diseases resulting in healthier crops and food products. Reduced post-harvest losses, longer storage life and reduced agricultural waste. Agriculture as a source for renewable raw materials for industrial production of such items as fuel, lubricants, plastics, pharmaceuticals and other consumer products, with significant environmental benefit. Opportunities for investment in modern and clean new enterprise.*

43. Access to global markets for Europe's food and agricultural production. *Reduced cost of agri-food production. Crops, and food and feed products of improved quality.*

44. Access to essential supplies from world markets. *Security of crop supplies. Availability of competitive supplies of raw material food and feed materials.*

45. Enhanced employment opportunities. *Renewal of agriculture and rural communities by providing profitable opportunities for farmers and incentives for new, young farmers. Diversification opportunities for farmers and rural communities. Creation of new small and medium enterprises throughout the agri-food chain. Source of new, innovative and interesting jobs. Creation of a biotechnology know-how in Europe.*

46. International and domestic credibility. *Playing a role in establishing world standards in agricultural production. Consistency in trade negotiations. Confirmation of the EU's commitment to the thoughtful and responsible development of new technologies underpinning the creation of a modern, sustainable and competitive economy. Europe as a partner in innovation in all sectors and in all phases of product development.*

BENEFIT DATA

47. Quantified in-use benefit data and experience is required to establish the exact nature and size of these benefits. Data is so far however only available from the United States, Canada and Argentina where products have been approved for marketing and production since 1995. The Table below gives a summary of benefit data

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obtained by Monsanto over a total crop area of more than 19 million acres in 1997 in the United States and which therefore gives an indication of what might be expected in the EU. Data cannot be directly compared because of different climatic, operating and crop production conditions.

TABLE
Monsanto cost benefit experience of on-farm use of biotech crops in 1997

Crop	Yield Benefit Per cent	Value Potential Per acre	Farmer Satisfaction Per cent	Repurchase Intention Per cent
Roundup Ready Soybeans	5	\$12–20	90	90
YieldGard Bt Corn	8	\$20–35	90	80+
Bollgard Bt Cotton	10	\$35–70	80	70+
Roundup Ready Cotton	5–6	\$12–30	90	95
NewLeaf Potatoes	5	\$60–140	85	90

49. The cost benefits are an expression of the sum of a number of elements: Primarily reduced cost of chemical usage on crops, energy savings in farm and crop maintenance and lower farm equipment costs. The measured benefits identified in the Table do not include any quantification of the higher quality of delivered products (e.g., reduced contamination by weed and other foreign seeds), and the general improved peace of mind for farmers as they tend their crops.

50. A more complete evaluation covering products from other companies is included in Attachment 5.

EU BENEFIT DATA

51. *At the time of writing, the EU has still only issued one product approval (in 1998) for unrestricted domestic production of a plant crop and one for import from third countries so therefore no real data is available.* Many further products are in the approval pipeline but have also been significantly delayed for procedural reasons in the regulatory process.

52. Thus, the EU has already missed four years in the important initial stages of improved commodity and production in the competitive global agriculture markets, while at the same time has missed the domestic opportunities of improved environmental performance and increased sustainability of agriculture, lower costs of production and greater opportunities for farmers.

53. The importance of this technology and its introduction is even more important to the EU than other world areas because of the structure of European agriculture and the common agricultural policy and its relationship to the newly agreed arrangements under the Uruguay Round. That agreement reduces the volumes of commodity agricultural products which have incurred a production subsidy, which can be placed by the EU into export global markets. The only way for the EU to enter such markets is to reduce subsidies. Thus the EU faces the dilemma—how to maintain farmer income and reduce subsidies. The answer lies in reduced production costs and increased farm efficiency which should allow the farmer to maintain income and profitability in the face of lowered subsidies.

54. The introduction of the new biotechnology into crop production can help in this process although it should not be viewed as a universal panacea. The other world areas with whom the EU is directly competing have already adopted this approach, which means that it is urgent that the EU also does so in order to preserve its competitive position in open world markets.

SUMMARY AND REASONS FOR LACK OF EU BENEFITS

55. Much of this lack of crop introduction and therefore lack of benefits can be laid at the door of the bureaucratic and slow regulatory process. There is no reason that the EU should be any slower in coming to the same scientific conclusions from very similar data packages as regulatory authorities elsewhere in the world.

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ATTACHMENTS

1. Industry comparison of EU and US approval timelines (as of January 1997).
2. EuropaBio position paper on the need to improve the operation of Directive 90/220 on the deliberate release of GMOs. EuropaBio Position Paper 22 July 1997. (See pages 328–331).

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3. EuropaBio position paper on the revision of Directive 90/220 (COM(1998) 85 final, 23 February 1998. (See pages 326–328).

4. GIBiP position paper on the revisions of EU Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. March 1998. (See pages 293–294).

5. James, C 1997. Global Status of Transgenic Crops in 1997. ISAAA Briefs No. 5 ISAAA: Ithaca, NY page 31. (*Not printed.*)

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2. Report on the review of Directive 90/220/EEC in the context of the Commission's Communication on biotechnology and the white paper. Commission of the European Communities, Brussels, 10 December 1996, COM(96) 630 final.

3. Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, 98/C 139/01, Official Journal of the European Communities, C139/1, 4 May 1998.

4. Regulation (EC) No. 258/97 of the European Parliament and of the Council of January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Communities. No. L43/1. 14 February 1997.

5. FAO, 1996. Biotechnology and food safety. Report of a Joint FAO/WHO Consultation. Food and Agricultural Organisation (FAO), Rome.

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7. WHO, 1995. Application of the principles of substantial equivalence to the safety evaluation of foods and food components from plants derived by modern biotechnology. Report of a WHO Workshop. World Health Organisation (WHO), Geneva. WHO/FNU/FOS/95.1

ATTACHMENT 1

Determinations of non-regulated status of genetically modified plant products at USDA (as of January 1997)

Company/Institution	Crop	Trait	Time required for determination ¹ Months
Calgene	Tomato	Fruit Ripening	~4.5
Calgene	Cotton	Herbicide Tolerance	7
Monsanto	Soybean	Herbicide Tolerance	8
Calgene	Rapeseed	Modified Oil	7
Upjohn	Squash	Viral Resistance	~29
DNA Plant Technology	Tomato	Fruit Ripening	5
Monsanto	Potato	Insect Protection	~6
Ciba-Geigy	Corn	Insect Protection	~6
Monsanto	Cotton	Insect Protection	~7.5
AgrEvo	Corn	Herbicide Tolerance	6
Zeneca/Petoseed	Tomato	Fruit Ripening	~8
Monsanto	Tomato	Fruit Ripening	~7
Monsanto	Corn	Insect Protection	~4.5
Monsanto	Cotton	Herbicide Tolerance	~5
Dekalb	Corn	Herbicide Tolerance	~7
Northrup-King	Corn	Insect Protection	~6
Du Pont	Cotton	Herbicide Tolerance	~5.5
Plant Genetic Systems	Corn	Male Sterility/Herbicide	Tol~6
Agritope	Tomato	Fruit Ripening	4
Monsanto	Potato	Insect Protection	5
Asgrow	Squash	Viral Resistance	6
AgrEvo	Soybean	Herbicide Tolerant	~4.5
Cornell U.	Papaya	Viral Resistance	~6.5
Average			² ~7

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¹ Approximate average time from submission to USDA to approval.² The average time for USDA approval was six months if the Upjohn squash product that was prolonged based on resolution of technical issues is excluded.*Genetically modified plant products approved according to European Directive 90/220 (as of January 1997)*

Company/Institution	Crop	Trait	Time required for determination ¹ Months
Rhone-Poulenc	Tobacco	Herbicide Tolerant	~9
Plant Genetic Systems	Corn	Male Sterility/Herbicide Tol	~24
Monsanto	Soybean	Herbicide Tolerance	17
Bejo-Zaden	Chicory	Male Sterility/Herbicide Tol	~18
Ciba-Geigy ²	Corn	Insect Protection	~25
Average			18-19

¹ Approximate average time from submission to rapporteur country to publication in the European Official Journal.² Eu delay for ~six months for resolution of technical issues.*Genetically modified plant pesticidal products approved by the US EPA (as of January 1997)*

Company/Institution	Crop	Trait	Time required for Approval Months
Monsanto	Potato	Insect Protection	20
Ciba Geigy/Mycogen	Corn	Insect Protection	12
Monsanto	Cotton	Insect Protection	20
Northrup King	Corn	Insect Protection	14
Monsanto	Corn	Insect Protection	19
DeKalb	Corn	Insect Protection	11
Average			16

Supplementary Memorandum by Monsanto Services International S.A./N.V.

In response to a specific request from the Committee made by telephone on June 16, this evidence relating to the environmental and societal impact of genetic modification in agriculture is further to the evidence already submitted and dated 4 June 1998. This evidence specifically relates to the experience so far gained from commercially introduced genetically modified agricultural crops.

AGRICULTURE: THE GLOBAL DEMOGRAPHIC FACTS

1. There are a range of estimates on the world's population growth and predictions suggest an increase from the current 5.8 billion to a peak in 2050 of some 10 billion. At the same time, this population must be fed and clothed and there is a limited and ultimately finite amount of available agricultural land on which to produce food and fibre for this growing population.

2. Currently, about 14 million square kilometres of land are farmed and without technical developments, it is estimated that some 40 million square kilometres would be needed to sustain the population growth, while at the same time increasing the standard of living. Nearly all of the most productive and accessible farm land is already under cultivation, and it is the quest for further agricultural land which is leading to destruction of the wilderness and tropical forest areas. At the same time, this productive land is subject to the onslaught of both man and the elements leading to the substantial loss of valuable topsoil and soil nutrients in many areas and to less and lower quality surface and groundwater.

3. The situation is different in developed and developing countries with the population of the developing countries striving to attain a standard of living comparative with those in developed countries. The first desires in many cases are a stable, more productive and higher quality source of food, which therefore depends on affordable improvements in agricultural capabilities. In developed countries where agriculture provides a more plentiful food supply, the immediate challenge is to provide that same food in a more environmentally sustainable manner and with compatible agricultural techniques. More worryingly on a global scale, it would seem that in recent years, the global human population has frequently consumed more food than it has produced.

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[Continued

4. Current production systems, although they can be honed, cannot provide a long-term and sustained response to these issues and problems. The application biotechnology to agriculture can help to provide some of the solutions. However, it is still a technology in its early development and the limits of the opportunity to deliver solutions are still therefore largely unknown. Similarly, it should not be regarded in the current state of knowledge as a universal panacea.

5. Nevertheless, from the data so far available, it is possible to gain an insight into the potential benefits which the application of genetic techniques can bring.

6. The first genetically modified plants were produced in 1982 and the first plantings in the field were carried out in 1986. In the intervening 16 years since the first plants were produced, around 25,000 field tests have taken place in 45 countries with 60 different plant species.

7. After gaining regulatory approval, the first products were commercialised in 1993 with currently 34 products approved in the United States, 30 in Canada, 20 in Japan, eight in the EU, three in Mexico and one in Australia. In the EU, only one food crop is permitted to be grown commercially.

8. In 1996, approximately three million hectares were planted commercially increasing to 12 million hectares in 1997 and a projected 26 million hectares globally in 1998.

9. From the experience gained from this long series of test and commercial operations, the benefits have been assessed and relate to a number of areas:

Reduced chemical input to agriculture as a result of the introduction of insect-protected, herbicide-tolerant and virus-resistant crops.

A shift to more sustainable and environmentally sound crop protection systems, resulting in reduced land erosion with improved ground and surface water quality and preservation of natural habitats from increased yields.

Reduced farmer exposure to agricultural protection products.

A reduced need for use of non-renewable fossil fuels in chemical production, transport and application.

Increased productivity per unit of useable farm land due to superior weed and insect control thus limiting the demand for sourcing new arable land.

10. Data from four crop examples are given below which illustrates the impacts of these crops in the local environment. In all cases, the information is from commercial experience in the countries concerned. The products were submitted to the regulatory authorities in each country who carried out a full examination of relevant data prior to approval of the products for commercialisation.

BOLLGARD® [INSECT-PROTECTED COTTON]

11. Approximately 730,000 hectares of genetically modified insect-protected cotton varieties were grown in the United States in 1996 accounting for approximately 13 per cent of the US cotton crop in that year. The crops were given the insect protection by introduction of genes derived from the naturally occurring bacterium *Bacillus thuringiensis* (Bt). Plantings rose to 900,000 hectares in 1997 with a projected crop of over one million hectares in 1998. In addition, insect-protected cotton varieties are cultivated in Australia (60,000 hectares) and Mexico (16,000 hectares) in 1997 and are expanding to China and South Africa in 1998.

12. The cotton plants have been genetically modified to provide protection against the three major cotton insect pests: tobacco budworm (*Heliothis virescens*), pink bollworm (*Pentinophora gossypiella*) and cotton bollworm (*Helicoverpa zea*).

13. Cotton consumes per crop, one of the largest amounts of chemical insecticides in the United States. From US data, it has been calculated that cotton growers that grew Bollgard cotton reduced their chemical insecticide use to control the targeted insect pests by between 85 and 90 per cent on the hectares where the insect protected crop was grown. This translates into a reduced consummation of about one million litres of chemical insecticides in 1996 and 1.25 million in 1997.

14. The increased effectiveness of pest control in these crops resulted in an average increase of 7 per cent in cotton production where the insect-protected varieties were cultivated due to lower losses to insects. Cotton growers averaged a net \$130/hectare income advantage as a result of lower chemical cost and higher yields. At the same time, compared with insecticidal protection, there is an increase in the number of beneficial insects due to specificity of the pesticidal protein which provides the protection of the crop.

15. Other world areas which could benefit from this technology include India (cotton cultivation of 6.3 million hectares), Argentina (0.3 million), Zimbabwe (0.1 million), Turkey (0.6 million) and the EU (0.6 million, principally Spain and Greece).

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YIELDGARD® [INSECT-PROTECTED MAIZE]

16. With an insect protection similar to that of cotton, some 160,000 hectares of genetically modified insect protected *Bt* maize were commercialised in the United States in 1996, rising to 1.2 million in 1997. It is projected that in 1998, some 8 million hectares or approximately 30 per cent of the US maize crop will be accounted for by *Bt* insect-protected varieties from a number of producers.

17. The modification of the maize varieties results in protection against the corn borer (*Ostrinia nubilalis*) which in areas of infestation can account for up to 20 per cent in yield losses with an average of 6.4 per cent. Prior to the introduction of the insect-protected varieties, there was no effective treatment for the pest.

18. In the maize crop, insect damage to the corn ear permits infection by fungal pathogens such as *Fusarium* which produces mycotoxins which are toxic and a suspected cause of some cancers. Use of YieldGard varieties prevents insect damage to the ear and thus eliminates the infection by *Fusarium* and the production of the *Fusarium* mycotoxins. The end result is a higher and more consistent grain quality.

19. As a result of the introduction of the new genetically modified varieties, tests by university groups have shown that grain yields have increased by 10-15 per cent with YieldGard varieties as a result of season-long protection throughout the plant. Improved performance of the crop in adverse weather or drought has been seen as well as the increase in grain quality. Maize growers have also seen improved net income of up to \$65/hectare.

20. Besides the United States, other corn borer infested maize growing world areas which could benefit from the introduction of YieldGard varieties include China (8 million hectares), Brazil (8 million), Mexico (6 million), Central European and the CIS (9.4 million) and Western Europe (7.5 million).

ROUNDUP READY® [HERBICIDE TOLERANT] SOYBEANS

21. Beginning in 1996 approximately 400,000 hectares of glyphosate-tolerant (Roundup Ready®) soybeans comprising 10 varieties from three seed companies were grown by some 10,000 growers in the United States. There were an additional 50,000 hectares under cultivation in Argentina. It is projected that over 10 million hectares of Roundup Ready®, or more than 30 per cent of the total soybean acreage comprising more than 300 new varieties, will be under cultivation in the United States in 1998. In Argentina, more than 4 million hectares of Roundup Ready® soybeans are projected to be planted in 1998.

22. Due to the warm and humid growing climate for soybeans, weed infestation is a major problem in soybean production. Weeds take light and nutrients from the growing crop and contaminate the final grain with foreign seed material. Prior technology for dealing with the weed problem involved soil-treatment with a number of chemicals prior to planting to reduce weed germination.

23. The advent of Roundup Ready® soybeans which are tolerant to the Roundup herbicide allows the crop to be planted and sprayed with Roundup® once and when the extent of the weed problem is observed. Being tolerant to glyphosate the soybeans are unaffected while weeds are eliminated. Roundup® is well-recognised for its environmentally sound characteristics.

24. As a result of the introduction of Roundup Ready® soybeans, academics, seed companies, commodity evaluation companies and Monsanto have generated detailed data which shows a number of benefits. The excellent weed control leads to an overall average of 5 per cent yield increase on areas where Roundup Ready® soybeans are cultivated. In-season herbicide use (in 1997) in the United States was reduced by between 11 per cent in the West Central area of the US to 30 per cent in the South East with an overall average of 22 per cent in Roundup Ready® soybean cultivation. Seventy-five per cent of soybeans farmers used only one application of Roundup® herbicide. The improved weed control also gave results in a reduction by one-third in foreign matter (e.g., weed seed) present in harvested grain. Adopted in combination with conservation tillage techniques, soil erosion also drops significantly.

25. For soybean growers, besides the peace of mind and less intensive production control, the benefits have translated into lower unit costs of production of soybeans which have provided income benefits estimated at up to \$40/hectare. (See *Monsanto Achievements 1997*).

NEWLEAF® [INSECT-PROTECTED POTATOES]

26. Since 1996, NewLeaf® *Bt* insect-protected potatoes have been in commercial production.

27. Many areas of potato production are affected by the destructive Colorado potato beetle which affects tuber quality and the introduced NewLeaf® varieties have high specificity for the targeted insect pests while leaving beneficial insects untouched.

28. As a result of the introduction of the new varieties in the United States and Canada, data generated show that insecticide use for insect pest control has been reduced by 40 per cent. Payable yields of high quality large

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[Continued

tubers have been increased and internal tuber defects have been reduced. The planned introduction of NewLeaf Plus, which combines protection against Colorado Potato Beetle and the potato leaf roll virus (PLRV) will lead to an estimated 80 per cent reduction in chemical insecticide use in potato.

29. A chemical balance comparison calculation of traditional potato production versus NewLeaf® potato cultivation in the United States has shown that over 40 per cent reductions in the following can occur: To produce insecticides for the US potato crop, 2 million Kgs of raw materials are used and the energy from 1,500 barrels of oil producing 1 million Kgs of waste. The 500 thousand Kgs of the produced insecticide is then formulated with two million Kgs of inert material to produce 180,000 containers of insecticide product which is then sprayed on the crop using 600,000 litres of fuel. At the end of this process, only some 5 per cent of the insecticide reaches the target pest.

30. As a result of cultivating NewLeaf® potatoes, the resultant net benefits to potato growers is up to \$280/hectare as a result of lower input costs and increased payments as a result of improved potato quality.

EXPERIENCE FROM OTHER COMPANIES

3.1 For a recent summary of the experience of other companies and institutions which have introduced genetically modified crops into agriculture, the paper by James (1997) should be referred to. (This paper has been provided with the evidence provided previously). [not printed]

EMERGING PRODUCT CONCEPTS

32. This paper only touches on the societal and environmental benefits which genetically modified crops may provide, since it only covers the first few products derived from plant biotechnology. Such concepts which are currently under study include: Improved nutrient content such as healthier oils, carbohydrates, essential amino acids and vitamins; increased yield; elimination of nutrients and allergens; value added products to replace energy intensive manufacturing such as biopolymers and biofuels; and human and animal disease prevention through the production of edible vaccines and dietary improvements. Each of these concepts presents a unique technological challenge and the products will require an appropriately adapted regulatory process to ensure they are safe for introduction.

23 June 1998

Examination of Witnesses

DR KENNETH BAKER, Director, Government Affairs, Europe-Africa, MISS ANN FOSTER, Director, Government & Public Affairs, United Kingdom and DR STEPHEN WATERS, Manager, Regulatory Affairs, Europe-Africa, Monsanto Services International S.A./N.V. called in and examined.

Chairman

324. Good morning, Dr Baker. Can I welcome you and your colleagues to Sub-Committee D and thank you very much for having agreed to come and give evidence to us to help us in our enquiry into genetic modification in agriculture. Could I start by asking you to introduce yourself and your colleagues and perhaps say which parts of Monsanto you come from? Perhaps at the same time you could say what is the extent of Monsanto's activities in this country and Europe at the present time.

(Dr Baker) Thank you, my Lord, and members of the Committee. We are happy to be here answering your questions this morning and providing what information we can. My responsibility is for Government Affairs for Monsanto in Europe and I am based in Brussels. To my left I have Ann Foster, who is UK-based for Monsanto and she looks after our Government and Public Affairs operations in this country and I will ask her to respond about our operations here. To my right I have Dr Stephen Waters who heads up our Regulatory Affairs operation for

Europe. Perhaps Ann Foster would like to speak to the operations here.

(Miss Foster) In the United Kingdom Monsanto trades under the name "Monsanto plc". We have three divisions: pharmaceutical, agriculture, food and nutrition. You obviously are most interested in our agricultural division which in the United Kingdom is primarily devoted to sales of our range of agricultural crop protection products. As you know, we do not undertake any commercial sales of genetically modified seeds in the United Kingdom, although we are undertaking trials for GM seeds on the basis of the licences which have been granted by the relevant authorities.

Chairman] Thank you very much for that background information. Perhaps we can move to our substantive questions. Lord Gallacher?

Lord Gallacher

325. Dr Baker, what crops are now being worked on? Is the focus still on herbicide and pest resistance or has it moved to development of more direct benefit

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[Continued]

[Lord Gallacher *Contd*]

to the consumer? Is your technology assisting developing countries?

(*Dr Baker*) If I may, my Lord, I think I would ask Stephen Waters to provide the answer to that question.

(*Dr Waters*) Currently we are working on somewhere around 20 different crops. The main focus is on those crops which are widely grown throughout the world and form the basis of our diet. These include crops such as wheat, maize, soybean and rice.

Chairman

326. What are called "commodity crops".

(*Dr Waters*) Commodity crops, yes. Also in the European context crops like sugar beet and oil seed rape. We are also working on a number of fruit and vegetable crops, including tomato, lettuce, apples, to give some examples, and a number of tropical crops such as sugar cane and oil palms. The sorts of traits that we are developing could be broadly classified into three different areas. The area which is the most advanced and which most people here are familiar with are the so-called agronomic traits. These would encompass such things as resistance to Roundup herbicides. This is being applied in a range of crops, including soybeans, maize, sugar beet, to cite a few examples, and traits such as insect protection, protection of crops like potato, cotton and maize against caterpillar pests. Further agronomic traits would be in the area of protection against fungal diseases, which is particularly important in the European context. Fungal pathogens cause significant losses in crops such as wheat and potatoes. We are looking at protecting potatoes against leaf blight disease (*Phytophthora*), and also wheat against a whole range of fungal infections such as head scab which causes about two billion dollars' worth of damage worldwide every year. That is a review of the agronomic traits. What you would perhaps describe as traits with consumer benefits would fall into a second wave of developments. In a number of the major crops that I have mentioned we do have programmes targeted at trying to improve the quality or safety characteristics of these crops. Some examples would be that in corn we are looking at the development of modifications in the oil content and oil composition in order to produce oils which result in reduced cholesterol levels. In the area of soybean we are again looking at oil content as well as oil composition. Some examples of products which are in development are oils with an increased stearate content, a fatty acid present in oils which is important in the production of margarines, so we are developing a product which has high stearate levels which could avoid the need for chemical hydrogenation during the production of margarines. Another example is cotton; we are working on modifications to fibre strength and fibre length, also the possibility of producing coloured cotton to avoid the need for chemical treatments to change colour. Another example would be rice. We are looking at increasing the vitamin content, also decreasing the content of allergenic proteins. This is a series of products which are still at the development stage, probably two to three years away from the

market as far as the earliest products are concerned. A third area is using plants as providers of raw materials, using renewable energy resources for the production of such things as pharmaceuticals, food and feed additives, also the production of biodegradable polymers in plants. Of the three waves, products are currently on the market from the first wave and the second and third waves are in development and these will lead to future products.

Lord Redesdale

327. The question was asking about developing countries. There seems to be a great deal of concern about the use of patent protection on products such as the ones you have mentioned, even if they have great value. Is there a concern amongst developing countries which are going to use these products that they will not be able to afford your products or that they are going to suffer from the development you are making?

(*Dr Waters*) Some of the things that I have mentioned do have an immediate fit in a number of developing countries. As an example, the insect protected cotton product which was commercialised in the United States about three years ago: we are looking now towards introducing that product in both India and China. Both of those countries have significant areas of cotton, so that this product could bring immediate benefits to those countries. On the question of future products, again some of the products that I cited, such as rice, with increased vitamin content or decreased levels of allergenic proteins, clearly have a good technical fit in south-east Asia covering the whole range of developing countries. Intellectual property protection is certainly an issue as far as we are concerned, in terms of recuperating the investment in those products, but in most cases that will not stop us moving forward with the introduction of new products. We also have a number of projects under the umbrella of an organisation called ISAAA, which is a non-profit organisation whose function is to transfer technology from developed countries to the developing countries. One specific example where Monsanto is involved is in the transfer of virus resistance into sweet potatoes in Kenya. This is a project which has been ongoing since 1990, in which a number of Kenyan scientists have come to Monsanto's facilities in St Louis for training in the basic techniques of genetic transformation. We have made available to the Kenyan research institutes certain technologies and patents including the virus protection technology. We have made this available free of charge for use in Kenya in order to develop local varieties which are protected against local virus strains.

(*Dr Baker*) Just to add to that, some of the developing countries which Dr Waters has mentioned, such as India for cotton, if they can move to using this technology to produce cotton themselves, they will also want patent protection within that country because if they purchase the product and want to promote it as, for example, Indian cotton, they will want protection for that particular market themselves. There is a commercial interest in the country of origin of the product that is going into international trade and it will

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[Continued

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be important for them to protect those markets through a patent. I think we will see as one of the developments sources of many of these new biotechnology products under development as the developing countries.

(*Miss Foster*) In terms of assistance to developing countries part of the problem is access to the technology, and particularly in terms of being able to afford it. We have just begun a project under the generic name of Micro-Credit where we are investigating opportunities of working with partners to provide no interest or low interest loans requiring no collateral so that communities can themselves use this technology. We have just announced a partnership with the Grameen Bank in Bangladesh to offer these facilities to local communities and local farmers. I could let you have more information about that. The Micro-Credit project is at its very early stage but it does involve Monsanto employees working with NGOs in developing countries to try and identify areas where this particular initiative could enable people in local communities to have greater access to these technologies for their own benefit.

Chairman

328. Could I come in and ask you about the no-tillage system? Is that a direction that you are moving in? What is involved and what sort of scale would apply?

(*Dr Waters*) Conservation tillage is a relatively recent innovation. What it is in essence is an agricultural system which avoids the need for ploughing prior to sowing. One of the great difficulties, particularly in dry climates, is ploughing results in a significant amount of topsoil erosion. As a means of avoiding erosion, systems have been developed whereby the seeds can be sown directly into the stubble of the previous crop. However, this requires chemical control of the stubble in order to avoid having the crop being suffocated by the weeds which emerge amongst the stubble. It involves a treatment with a non-selective herbicide followed by direct drilling of the seeds into the stubble. As the crop emerges, it does not face competition from the weeds in the stubble; it maintains coverage of the topsoil which protects against erosion and it also creates a favourable climate for insects and other organisms, so it is a more environmentally friendly approach to the production of arable crops such as corn and soybean. This technique, I should say, has been developed independently of biotechnology and has been in operation for probably the last five to 10 years in the United States, Argentina, Brazil and to a certain extent in southern Europe. Some of the crops developed through biotechnology do have a good fit with conservation or no-till in that it provides more flexibility for farmers to be able to sow a crop which is tolerant to the specific herbicide which is used to kill off the weeds in the stubble from the previous crop, and so the introduction of herbicide tolerant crops such as Roundup Ready soybeans is encouraging a shift towards the use of conservation tillage in order to derive all of the benefits that I mentioned from conservation tillage.

Lord Jopling

329. Is your company worldwide doing any work on animal genetics? My second question is to ask you to speculate and imagine yourself being in front of this Committee in 20 or 30 years' time. Could you just speculate as to what you think might be coming in the realm of practical agriculture in that space of time as knowledge about genetics becomes much better? For instance, many of the things you have told us you are doing this morning are very closely focused on dealing with insects or with other pests. I give you one example which has been delayed, and that is the possibility of a nitrogen fixing wheat which I can remember being told 15 years ago would be in existence now, but it is not. I know there are difficulties. If you could create a nitrogen fixing wheat that would hugely change the face of the earth in many ways. Wheat could be grown where it is not now. Yields would be hugely increased. The effect on other wheat growing areas would be immense. You know all the arguments. Please speculate as to where you think we might get to with all this in 20 or 30 years' time.

(*Dr Baker*) My Lord, that is a difficult question because there is no precise answer. In terms of work we were doing on animal genetics, I am not sure what you are referring to in particular there, but to my knowledge we do not have any extensive work going on in the area of transforming animals of the nature of Dolly the sheep. I assume that is what you are referring to. In terms of where we might be in 20 years' time in terms of practical agriculture, the fact that nitrogen fixing wheat is not available does not mean that it is not a good idea. It is simply a very difficult technical problem to achieve that. Stephen, maybe you might want to talk a little about that. In my terms it is a bit like asking the electronics industry 30 years ago where would they be now. I think if you look back predictions have been all wrong, so that is why I say it is a difficult question to answer.

(*Dr Waters*) I would be happy to speculate a little bit. The vision that we have perhaps even extends beyond 20 to 30 years from now. Our vision is that we need to be working towards more sustainable production systems given that the amount of area which is available today is essentially the amount of area that we are going to have available in 20 or 30 years' time to produce all of the food that we need. In that time-frame the demand for food is expected to triple and therefore we are faced with the challenge of producing three times as much food on the same area of land. That poses all sorts of challenges in terms of increasing the amount of productivity per unit of land but at the same time decreasing the environmental impact of those production systems, and so my vision is that we will be dramatically increasing the yields of crops, either directly through the introduction of genes which can increase the levels of harvests, or indirectly through introducing genes with tolerance to stresses such as drought or salinity, probably a whole host of mechanisms that one can imagine to try to increase the amount of production per unit of land. At the same time the example you mentioned of nitrogen fixing

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genes would allow crops to fix their own nitrogen and avoid the need to apply nitrogen fertilisers, which is a much more sustainable approach to production. I see us working on the balance between increasing productivity and decreasing inputs.

Chairman

330. What do you mean by increasing yields directly?

(Dr Waters) Yield is essentially the production of carbohydrates. For instance, in wheat a large part of the wheat grain is starch and so if one could modify the starch metabolism pathway in plants, one could envisage increasing production of starch from wheat.

Lord Jopling

331. You see, you continually as a company come back to this business of increasing world population and diminishing resources to feed that population. If I may say so, that is a card which has been played ever since Malthus started playing it all those centuries ago. It is a situation which has never really occurred because the capacity of mankind to produce food—and I am talking about the developed world, I am not talking about the undeveloped world—has outstripped the growth in population, contrary to what Malthus and you are saying. Do you not feel slightly embarrassed by just tagging on to a somewhat discredited argument?

(Dr Baker) If I may answer that, you have to look at the whole picture. To some extent your question was regarding where would we be 30 years from now, and which must include the total picture. There is an issue of a growing population for whom food needs to be provided, not only in the developed world. At the same time, as in past years, we need to be conscious of the fact that in many ways we cannot continue to provide ever increasing amounts of food with the techniques that we use now. Coming back to your question about what will the picture be in 30 years' time, I would say to you that one thing that will be different will be what we now consider to be the chemical industry. There will be a lot of those products which are produced by the chemical industry which will be produced by farmers in crops much more efficiently. One other effect, if we follow what Dr Waters was saying, will be a coming together of the pharmaceutical and nutrition and health business to somewhere in the middle where much of the health care of the population will be provided through the food supply. That health care will be available to everybody, not just to the developed world, simply because you can produce crops anywhere there is fertile land. One would not have to put up a big factory; it would simply be replaced with a crop that is suitable to plant. We do need to provide food for that growing population and this is one of the technologies that can help. It is not necessarily the only one.

Lord Rathcavan

332. It is said that one of the problems of public acceptance of GMs is that most of your GM development has been in commodity crops. As far as

I know, in this country the only wholly GM products the consumer can buy are tomato paste and vegetarian cheese. I am not sure whether Monsanto itself is involved in a whole GM product yet. Evidence seems to suggest that if you want to get more consumer acceptance of GM products the consumer will have to see the benefits. You mentioned lettuces and apples earlier in your comments. When do you see a Monsanto whole GM product being on the market here in Europe?

(Miss Foster) I will respond briefly although I will refer to Dr Waters about the actual timescale. You are right in that the first imported crops in Europe have been genetically modified soya and maize. It is absolutely true to say that it is quite difficult to emphasise the consumer benefits as these particular agronomic traits (herbicide resistance) are so far back in the chain. As we work on other agronomic traits it will be possible for the consumer to see more benefits, particularly in the reduction in chemical applications. We have already seen this with potatoes which have been marketed in Canada, the insect protected potatoes which require much less application of chemicals in their production and because consumers can identify with this they have been very favourably received.

333. The farmer can identify with that, not the consumer.

(Miss Foster) No, the consumer as well.

334. How can the consumer identify with that?

(Miss Foster) Because I think consumers are quite well aware that conventionally grown potatoes do require chemical applications both pre and post harvest, and if it can be explained to them by company information that this form of producing potatoes enables a reduction in the use of chemicals they will be well received. In Canada and the US they are called New Leaf potatoes and these have been sold direct to consumers through the supermarkets with supporting information telling them about the reduction in chemical use. They have been very well received on the market. In terms of future products, which I think links to a previous question, I can see the development of products with an improved nutritional profile, particularly in the alteration of fatty acid content and also vitamin and mineral content. I can envisage products with increased antioxidant content and antioxidants are believed to have protective factors against the incidence of certain diet related cancers. In terms of the timescale I will ask Dr Waters to answer that.

Chairman

335. Before we come on to the timescale, would you expect those to have great consumer attraction, those products?

(Miss Foster) Yes, I would think so, because I think there has been considerable evidence that consumers are very much conscious of the relationship between diet and disease. The popularity of low and low saturated fat products have shown that consumers would find these benefits attractive.

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[Continued]

[Chairman Contd]

(Dr Waters) In terms of the timescales, the most advanced product is the high stearate oil which I believe is targeted to be commercialised in the United States around 2001. We could expect that in Europe it will be available several years after that.

Lord Rathcavan

336. Sorry, I did not catch what you said.

(Dr Waters) High stearate: stearic acid is a fatty acid which changes the chemical properties of the oil which is used in margarine production.

337. If you were to go into a supermarket and ask people, "Would you prefer to buy X product with antioxidants?", do you think they would understand what you were talking about?

(Miss Foster) It would have to be explained to them but if it was explained in terms that people do identify with quite readily, there is in the United Kingdom enormous interest in the link between diet and disease. Yes, it would be very popular.

(Dr Baker) Certainly in relation to your question, Lord Reay, about whether consumers understand, in the case of the potatoes that Miss Foster was talking about, the label on the potato stated that these were genetically modified and produced without the use of herbicides, which was a sufficient message for the consumers to understand and to want this product.

Chairman

338. Was it a more expensive product like an organic product or a cheaper one like the tomato paste?

(Dr Waters) A premium was asked but the farmers were also paid a premium because not only could they avoid insecticide applications but the quality of the potato was improved. The farmers are paid a premium based on the size and shape of the potato so farmers benefited, and also the consumers because of the improved quality of the potato, and they were prepared to pay a premium in recognition of the improved quality but also the fact that they had been produced using less insecticide. The customers put a value on that and they were prepared to pay for it.

Lord Wade of Chorlton

339. May I just follow on from the point that Lord Jopling was making? In fact we have a billion people in the world today who are undernourished by our standards and frequently we see harrowing scenes of people starving to death throughout the world, so we are not completely dealing with the demands as they stand at present. We have increased our production to meet extra demand by the use of fertilisers and insecticides. That has been one of the main developments that has made it possible. Would you argue that using your kinds of products we would be able to reduce the use of fertilisers and insecticides and such other aids to production?

(Dr Baker) The simple answer to that is yes, and in fact we have provided you I think with some further evidence laying that out exactly. To give you some

examples, if one takes cotton, which is produced in both the developing and developed world, in the on-farm use of that, studies by various academic groups have shown that farmers, when they plant this product, use somewhere between 85 and 90 per cent less chemicals to control that crop. When you think about cotton, in particular as the crop with the highest use of chemical insecticides, that I think illustrates the point that you are making. If you are talking about the developing world, of course what is happening is that the plant is growing its own protection in the soil and so there is no necessity to import it or develop it or to ship it around to those particular communities.

340. May I now ask my next question. Would you like to comment on your experience of bringing GM crops from the US to the EC, and what is the EC indecision and unpredictability that you referred to costing Monsanto?

(Dr Baker) In terms of the relationships between the United States and Europe, the regulatory system that we have here is somewhat more complicated in terms of the way it operates than that in the United States. I would characterise it as less efficient I think overall. The regulatory stringency in terms of the evaluation of the data is, I would say, roughly equivalent in both places. What that is leading to in particular with these crops which are globally traded is an imbalance in the approvals for these products around the world. As commodities in particular are widely traded, that impacts on the trade of those products because if they are not approved in one place then they cannot be imported, or if they are produced in one place and not approved in another place then there are problems with importing them. In terms of what does it cost Monsanto, that is a difficult thing to put a figure on. I can tell you that the delays that we experience here, which are to a large extent due to paper pushing, are not a question of the evaluation of the product which is all done very well scientifically. It is a question of working out what the regulation really means in terms of its operation and bureaucracy and so forth, which means that we need to keep people employed while all this is going on, so that we are ready to answer questions. Those delays can be several years and we are using people sitting around waiting to answer questions about the bureaucracy, not about the scientific nature of the products. I cannot put a figure on the cost, but it is actually costing us a lot in people in a non-productive mode.

341. So in terms of the safety precautions taken both in the EC and in America they would be about equal. It is not a question that any system is different from another in terms of the certainty that it gives about the product being safe. It is merely about the way that the system is administered that you would say is less efficient in Europe than it is in America?

(Dr Baker) I would say that is the prime difference. In terms of safety evaluation, maybe my regulatory colleague can comment.

(Dr Waters) I think if one looks at the data which is provided and the safety assessment which is submitted in Europe and one compares that to the safety assessment which is submitted in the United

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States and even in Canada, Japan and Australia, you will find a high degree of commonality in the type of information which is required to come to a conclusion on safety. Where Europe differs, as Dr Baker said, is in the procedures which are much more complex in Europe because it involves a review by 15 Member States rather than a single centralised authority. Obviously 15 countries means a range of cultures, different perceptions of risk, and so in a European framework it is difficult to come to an agreement on what is an acceptable or unacceptable risk. Those sorts of discussions are essentially what have slowed down the decision making process in Europe.

(*Dr Baker*) Some of those are unavoidable. Let me give you one example: the translation of any material into all of the different languages of the Community and making sure that each translation means the same can lead to extensive delays and problems. I am not suggesting that we should do away with the languages but there is an issue.

Lord Rathcavan

342. Has your experience of the EC regulatory system differed depending to which Member State you apply?

(*Dr Waters*) The answer can be divided into two parts. The first part concerns research and development and the second part concerns applications to market products throughout the EU. As far as research and development is concerned, we have been testing products across Europe since 1990. We have experience in about 12 different countries now. I would say that the situation today is relatively consistent. In the earlier years after the adoption of the European Directive there were much more divergent approaches because it was a learning process for both notifiers as well as regulatory authorities. Over time, because of dialogue between the various competent authorities, there is now a much more consistent approach to dealing with risk assessment for Research and Development purposes. Obviously there are still differences between countries. We spend a lot of time filling out different application forms in different languages to test the same plant material. For the moment there is no procedure for having an EU-wide authorisation which allows you to test plant material in multiple countries. It is still very much a direct contact with the regulatory authorities on a country by country basis. As far as marketing is concerned, we have had experience with four different countries in Europe with 10 different products. Our experiences have differed. As we discussed a few moments ago, those differences really have not been at the scientific level. The type of data which is expected by the different countries is quite consistent and our experience has been that the review process has been science based and has been quite timely. The difficulties have come once the application has been forwarded to the rest of the Community so, therefore, to respond to your question I think that our experience across those four countries where we do have experience is quite consistent. It is only at the later

stages of the process that we start to run into procedural difficulties.

Chairman

343. Could I ask you what you think about the Commission's proposed amendments to the Directive 90/220? You are very critical in the paper that you have kindly sent us about Directive 90/220 as it exists. Could you say a bit more about what you think of the proposed revisions to 90/220? Are there any major problems with the existing Directive not addressed by the Commission?

(*Dr Waters*) Perhaps rather than go into all the details that are outlined in the written evidence I will respond by outlining the key aspects of the regulations as far as industry is concerned.

344. Of the proposed amendment.

(*Dr Waters*) Yes. I think in general terms the way we would define a workable regulation is a regulation which is firstly based on sound science; secondly that the approvals are given in a timely manner and there is a degree of predictability about the procedure and the amount of time that it takes to complete the safety assessments. Thirdly, we think regulation should be consistent with international regulations, and fourthly, the administrative procedures should be proportional to the amount of risk. If one applies those basic criteria to the Directive, as it stands today, it clearly falls down in each of those areas. With respect to the revision, I think it does go some way to correcting the inadequacies of the current Directive. To give you some examples, there is a genuine effort to try and bring clarity to how one goes about risk assessment. The current Directive does not provide clear indications on what one does with the information which is provided, how one processes that information and how one comes to a conclusion about whether a product provides a threat to the environment or to human health. The new revision proposes a standardised approach to conducting the risk assessment, so that is certainly a positive aspect. Another positive aspect is the inclusion of referral to the European Commission's Scientific Committees. This should strengthen the scientific approach to the safety assessment. Another positive aspect is improvements in transparency of the process. There are now provisions for public consultation during the review which we consider to be positive. On the other hand there are certain weaknesses which the Commission itself pointed out when it reviewed the Directive at the end of 1996, and some of those recommendations have been taken into account. Others have not.

345. Could you say something about the ones that have not in your view?

(*Dr Waters*) An example would be the timeliness of decisions. One of the major barriers to approvals has been delays which have taken place particularly in the phase of drafting of the Commission decision, and voting by the Member States. Time limits have been introduced but not for every stage of that process, so there is still a reasonably high degree of uncertainty

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about the procedure itself and how long that procedure will last. Other concerns are that the complexity of the Directive has actually been increased by placing time limits on the authorisations. It is now proposed that any authorisations must be renewed every seven years. This adds to the lack of predictability and the uncertainty in the procedure from the point of view of companies who are investing in the development of products. There is only the certainty that products will be authorised for seven-year periods and it is not assured that the authorisation will be renewed. Also I mentioned risk and administrative procedures being linked. The new proposals for the Directive, although they categorise products in the Research and Development part of the Directive, they do not do that under the marketing part of the Directive. For example, products which are imported for processing purposes but which are not intended for planting in the EU must undergo a similar safety assessment to products which are to be planted here. There is no attempt to try and introduce simplified procedures for products where the risk is considered to be lower than it is for products which are planted in the EU.

Lord Jopling

346. In the paper you kindly sent us, in paragraph 21 you say: "... some Member States are using national variety registration procedures to add further conditions to the marketing of GM varieties. These conditions are, in some respects, contrary to Community (90/220/EEC) decisions, are not science-based and are an additional burden to industry, which decreases the competitiveness of European agriculture without providing additional safeguards." Can you expand on that statement and can you tell us which are the Member States you are referring to in the evidence you put before this Committee?

(*Dr Waters*) Perhaps as a word of clarification first of all, before a genetically modified variety can be marketed in the European Union it requires clearance under a number of pieces of regulation. It requires authorisation under the 90/220 Directive, it requires authorisation under the Novel Foods Regulation and it also requires that the variety enters national variety registration procedures which are usually administered by national Ministries of Agriculture. The purpose of those variety registration procedures is to ensure that the product provides agronomic advantages for farmers and also to characterise the identity of a particular variety. The example that I was referring to was not a Monsanto product but it is the first product which has been grown in the European Union, which is the insect protected maize. This product went through the 90/220 review process. It was subjected to a thorough environmental risk assessment, where all the possible questions that one could ask about interactions with the environment were addressed and the product was approved for planting throughout the European Union without any specific conditions attached to that with respect to monitoring for interactions with, for example, microbial populations in the soil and in the gut of the animals which are fed with the maize. In light of this 90/220 decision the

varieties were then registered under national variety procedures in both Spain and France and in both cases the variety approval was given on the condition that further studies were carried out to investigate interactions with micro-organisms and other organisms in the environment. The concern there is that these interactions were considered under the European procedures, and they were considered to represent no adverse risk for the environment, yet because varieties had to go through this additional regulatory step these Member States used this as an opportunity to attach additional conditions, relating to risk which had previously been considered to be negligible.

347. Do you know of any other countries besides Spain and France who have been resorting to these tactics?

(*Dr Waters*) To my knowledge these are the only two countries where genetically modified varieties have been approved for cultivation in the EU.

Lord Redesdale

348. In the evidence you gave, in paragraph 16 you said that many considerations should be out of scope. Could you give us some indication of what considerations you think should be out of scope for the regulators?

(*Dr Waters*) In the written evidence a number of examples were given. Some of them date back several years but they illustrate the way in which the Directive is being interpreted differently by different Member States, and perhaps part of the problem lies in the lack of clarity in the scope of the Directive itself. To give you a couple of examples, the first one concerns criteria which have no relation to protection of the environment or human health, which is the objective of the Directive. An example of this is objections which were raised by Member States concerning the labelling of seed bags as well as food products derived from the genetically modified grains. Clearly this labelling is a criterion which is not related to the safety of the product, but Member States raised objections to the marketing of products on the ground that the labelling proposals were inadequate. That is one example of a non-scientific criterion being used as part of the safety assessment. Another example, which does relate to scientific criteria which would be covered by other legislation, is the example of the presence of pesticide residues in the genetically modified grain. These aspects are covered by the Plant Protection Directive 91/414, yet these questions were raised in the context of the 90/220 Directive and should have been considered to be out of the scope of 90/220, but within the scope of another piece of legislation.

349. Going back to the labelling question, what might be considered out of scope then would perhaps raise its head in a different area in the issue of segregation. You would not know how to segregate certain types of foodstuff. You talk about very strict guidelines and constraints on what should be regulated. Do you not think those could actually be counter productive in the long term?

(*Dr Baker*) In terms of the labelling under the 90/220 Directive, as Dr Waters was saying, it concerns

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the product, in other words in that case the seeds which are being sold. They would be labelled anyway. We in fact put that in our submission. In response, it was the Commission which was arguing that labelling was out of scope to be included in the regulation, even though *de facto* you would sell those seeds labelled. In other words, this question of out of scope is in fact more to do with the lack of clarity in the regulation itself as to what is included and what is not included. We have no problem with it, but it must be clear in terms of what we are supposed to provide in terms of evidence and data and that is where the debate comes from to a large extent.

(*Dr Waters*) As a follow-up to the discussion on labelling, the response of the Commission to this impasse was to actually go back and modify the Directive to require labelling of the seed bags even in the absence of any environmental or human health concerns. Therefore, while the Directive was being modified, all of the product approvals were put on hold and companies initially volunteered to label seed bags as containing genetically modified seeds; it is now mandatory to do so. This was an example of an out of scope objection but it nevertheless blocked the approval process and in order to remove that blockage the Commission resorted to modifying the Directive to make this an acceptable objection.

Lord Gallacher

350. On labelling for information, at paragraphs 19 and 37 of the Monsanto evidence there is reference to labelling for information being a barrier to trade. Would you like to elaborate on that?

(*Dr Baker*) I think first of all one should say that this is a comment rather than a point of criticism. Labelling for information can always be instituted by any community for whatever reason. Generally speaking, labelling is information which relates to some type of safety or health consideration about a particular product but, as has recently been done here in Europe, labelling can be required for informational purposes, and also to tell the population what is in the product. However, in this particular instance with commodity crops which we mentioned earlier on, they are traded internationally and, of course, there are derived food products from them. Then there are requirements in that trade as to how you label products from other nations and therefore one gets into an argument about whose labelling regulation is the best and what is consistent with the international trade rules. So there is an area here which needs to be looked at in terms of the effect of labelling on international trade and on other third countries. It is not to say that there is not a trade issue here, but one needs to be a little careful as to how this is all implemented.

351. In the evidence which the Sub-Committee has been having on this subject, I think it would be fair to say that most of it has signified that consumer acceptability is enhanced if labelling is adequate. Do you agree with that?

(*Dr Baker*) I think we have said that earlier on. If we take the example of the potato, in fact even though

they were higher priced, they were labelled and there was increased consumer uptake of that particular product, so, generally speaking, yes, I think we would agree with that.

Lord Wade of Chorlton

352. Could I just ask a further question on labelling. Do you think then that there should be some international labelling standards that would help with these international products and who might do it?

(*Dr Baker*) I would say there should be some consistency in international standards.

353. Would you see it as something that the WTO might be asked to look at?

(*Dr Baker*) Undoubtedly it would be.

(*Miss Foster*) These issues are also addressed by Codex's evidence.

354. You have been involved in marketing GM crops now, as you have just explained, in several countries. What lessons in allaying public concern have you derived from these experiences and what response has there been so far to your new advertising campaign?

(*Miss Foster*) One of the lessons that we have learned is that we were marketing GM soya in Europe before there was any agreement at EU level on labelling requirements. In the United Kingdom the situation was helped vastly by the fact that we did have a voluntary code of labelling devised by the food industry. One lesson to be learned is that it really does help if all these provisions are in place before the food is marketed, otherwise people have this sense that it is there by stealth and that is not the intention. In the United Kingdom we are lucky in that the IGD, the Institute of Grocery Distribution, has devised a voluntary code of labelling which is being followed by the United Kingdom food industry and that has been very helpful. We welcome the fact that we do now have an agreement at EU level on labelling provisions. The importance of giving consumers information has been a very important lesson and that means information before, during and after the introduction onto the market. Again we have to acknowledge all of the activity by the United Kingdom food industry, both manufacturers and retailers and the Government, in terms of giving consumers more information. As a company, we were of course so far removed from the ultimate market that we did not initially become involved in this process, but we very much welcome the efforts by those who were much closer to their consumers and who knew the kind of information and reassurances that people required. One of the areas that people are still unsure about is the degree of regulation that this food goes through before it is permitted on to the market and I would certainly like to think that we would be able to reassure consumers more in terms of the regulatory process. We have to bear in mind that in the United Kingdom we have been introducing this food against an overall background of consumer concern about food safety, about risk assessment and about confidence in the regulatory authorities. I hope that a lot of these concerns will be addressed by the

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creation of the Food Standards Agency. As to the response to the new advertising campaign, we are encouraged by this. It has been running now for almost four weeks. The feeling was very much that it was time for us to come out and support the rest of the food industry and not put the entire burden on them, but to take responsibility ourselves for providing more information, so there has been a public information campaign where, as you know, we have acknowledged quite openly that there are differences of opinion. We believe that it is important that people understand this and they have access to the range of opinion about genetic modification in the hope that people will read the available information and make up their own minds. We publicise a call centre and our website address. So far, we have had over 2,000 calls to the call centre and 700 of those people have wanted to speak to our live operators, and mostly they have been questions from the everyday consumer wanting to know more about the science, the regulatory system, and the products in which these foods appear as food ingredients. We have sent out over 1,000 information packs and these information packs contain information from a variety of sources. We have been careful to include information from a range of different sources, from the Food & Drink Federation, from the IGD (Institute of Grocery Distribution)—the survey they did on consumer attitudes—and from the Institute of Food Research giving more information and in very straightforward and simple language about genetically modified soya. We have had about 7,000 visits to our website, so we are very encouraged by the response. Yes, there has been some criticism of the campaign, but in acknowledging that it is a controversial issue, we expected that there would be some criticism. Our overall reaction is that it has been a very positive exercise and we have received a lot of support from other parts of the industry. We have no regrets at all about embarking on this course of action.

355. It would appear that GM crops have been much more accepted by the consumers in the United States than they have in the EC countries. Why might this, do you think, be the case?

(Miss Foster) There have been a range of suggestions put forward for this. United Kingdom consumers are quite suspicious about the application of science and technology to the food supply, whereas in the United States consumers there are much more ready to accept scientific progress. There is also a distinction in the degree of confidence people have in the regulatory agencies. The Food & Drug Administration has developed over the years a degree of confidence that is not shared by United Kingdom consumers in our regulatory process for reasons that I think have been well rehearsed and we all understand. I think these are the two main reasons and there are certainly distinctions that we do have to take on board. It has also been suggested that in the United States consumers are much more relaxed about the argument that this brings benefits to the US agricultural industry, whereas again in the United Kingdom people do not appear to be as persuaded by arguments that GM technology could bring benefits for farmers.

Lord Jopling

356. Do you not sometimes feel that the reassurances that you give the public are somewhat over-comforting? I notice in the current campaign that you have, and I quote from it, you say that "rigorous tests have been undertaken throughout Monsanto's 20-year biotech history to ensure our food crops are safe and nutritious as a standard alternative". Dr Waters, I wrote down what you said a few moments ago with regard to maize and you said that it had been introduced, "...where all the possible questions...were addressed...", yet since that has happened, there has been a good deal of publicity, as an example, with regard to genetically modified maize with regard to possible impacts on lace-wing insects. Now, I do not want to get into the particular case of the lace-wing because that work, I understand, was done in a laboratory and in practical terms it seems extremely doubtful whether the lace-wing can get at the larvae of the corn borer. I do not want to get into the detail of that, but it is the principle. Can I ask Dr Waters, when all possible questions were addressed with regard to that type of maize, was that particular possibility addressed at that time or was the impact on the lace-wing a surprise to you when this scare story appeared from the laboratory work in Switzerland? I think it probably was a scare story. What I am getting at is, is there not a whole raft of secondary impacts of introducing genetically modified organisms which cannot possibly be covered in the initial stage of certification when you tell us, and I quote again, I rub your nose in it, as it were, "all possible questions were addressed"? It is impossible in scientific terms to address all possible questions when you are introducing something because there are so many other issues, like a different type of lace-wing problem, that could exist. Is there not a whole range of these things under the surface which could appear and does this not alarm you because it alarms the public?

(Dr Waters) I will certainly choose my words more carefully next time, and I should not have been so emphatic or so black and white. Clearly there is always a degree of uncertainty about any new product introduction. I think what the safety assessment tries to do is to establish beyond any reasonable doubt that the products are safe for the environment and for human health. One can imagine all sorts of questions, and the most obvious ones are certainly addressed as part of the safety assessment. Clearly one cannot address every imaginable question. Having said that, there are provisions in the Directive that once new scientific information does become available, such as the information you were citing, clearly this information would have to be referred to the regulatory authorities who would reconsider the assessment that they had done previously in the light of this information. In the specific example you cited, this clearly was addressed in the safety assessment, although this experiment that you referred to related to a product from a competitor company, but, generally speaking, the question of the effects of these plants on beneficial insects, such as lace-wings, has been examined in the course of the safety assessments. For

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example, in the case of Monsanto's insect-protected maize, we actually measured the levels of beneficial insects in the field during our research and development programmes, prior to submitting the marker applications. The results of these studies, which are field studies and which we consider to be more relevant than the results from a laboratory study, although we should not dismiss that because it is clearly important information and we should take that into account, but the question was asked and the question was addressed under the field conditions and the results of those field studies demonstrated that there was no impact of the *Bt* protein in the maize plants on the populations of the lace-wings. On the contrary, the levels of beneficial insects in the transgenic plots was actually higher than it was in those plots which had been treated with insecticides, so there were positive indications on the impact on beneficial insects. To go back to your point, clearly there is no absolute answer. One can conduct all of the safety assessments to prove, with reasonable certainty, that the product is not going to present a risk and one has to move forward on that basis, but leaving open of course the possibility to gather new information after the product has been commercialised and to continue to evaluate the safety of the products which have been marketed.

357. I think, if I may say so, that is one of the most revealing answers we have had in this enquiry. Just let me try a little further. You agree in that answer that the introduction of crops like this is in a way a leap in the dark, but so is the introduction also, I would agree, of new pesticides, new chemical applications to crops. I think the key question the public want to know is, is this leap. the extent to which it is a leap in the dark which we seem to agree about, a bigger leap in the dark with genetically modified crops than anything else we have known in the past in terms of agricultural development?

(*Dr Waters*) I would respond to that by saying that we would have a great deal of information prior to launching one of these products commercially. For example, in the case of soya beans, they have been cultivated and consumed for centuries, so we have a tremendous amount of information about the interactions between soya beans and the environment and also in nutritional terms, so one has to start the safety assessment from that platform. We are not talking about the introduction of completely exotic species or completely new molecules; rather we have a high level of understanding about the crop that we start with, and the genetic modification is a simple modification in terms of the number of genes which one introduces relative to the number that are already present in the soya bean plant. We are talking about tens of thousands of genes which are already present and, in most cases, we are adding only one or two genes, and because of the minor changes, one can focus the characterisation on the changes which are made. Before a product can be authorised for marketing one has to characterise the changes which have been made and one has to demonstrate that those changes are stable both over time and also in different

genetic backgrounds and so that demonstration of stability allows us, at least to some extent, to project forwards and extend our conclusion of safety from the present to the future. That is the sort of assessment which needs to be done up-front, but that is not to say that these products are then put on to the market without any follow-up. On the contrary, certainly it is in our interests to make sure that the products that we market maintain the properties that we have demonstrated prior to launching them and we need to ensure that our customers are satisfied that the product is working as they would expect, so there is a whole system of product stewardship in place which allows ourselves, the distribution chain and our customers to follow the product under a commercial setting, and this network provides a mechanism for feedback on the product performance and any adverse effects, should any appear, subsequent to commercialisation. That sort of information will be quickly fed back to Monsanto and we would respond accordingly.

Lord Wade of Chorlton

358. Could I just follow on from that question because it is a very interesting point that Lord Jopling has raised. I seem to remember that when Professor Klausen developed the landrace pig in Denmark in the 1950s, which he did with traditional breeding methods, and there was no use in those days of biotechnology, it was a long time before he bred out all the throwbacks that came as a result of his change in breeding patterns. The outcome of this new pig was enormous because consumers had a different type of the product which they wanted. Would you agree that in fact that system of developing new breeds or new products as a result of traditional breeding methods is just as likely or in fact is probably more likely to produce something where you do not know what might come out of it than the GM produced new products? Would that be your view?

(*Dr Baker*) I think it is certainly true to say that the regulatory stringencies for what you might call traditional products are not at an equivalent level, which is I think really what you are asking, and it comes back to Lord Jopling's point.

359. But, as a science, that is the issue. Here we are in the position where for a long, long time it has been the economic need and pressure to improve continually the products that we are dealing with in the agricultural world and there are plenty of examples of how this has happened in the past, but we have used traditional systems. Those traditional systems are not in themselves necessarily simple or straightforward, as I know from experience, and they create all kinds of side-effects unless and until it becomes pure. Would you argue from a scientific point of view that the present methods, using GM and biotechnology, to produce new products and breeds is a cleaner, a more precise system of doing it than the old system of breeding and developing new products and new species?

(*Dr Waters*) It is a new tool for breeders. Breeders will continue to hybridise existing varieties and select

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out those offspring which provide the best performance. The introduction of genetic engineering allows the breeder to be more specific in what he does. For example, using traditional breeding methods, he may be able to produce progeny which have improved resistance to disease, for example, but there may be associated with that a decrease in the yield potential, simply because one is dealing with multiple genes and multiple interactions. In the case of biotechnology, the breeder is now able to introduce a specific gene for disease resistance into a high-yielding variety without having to be concerned, or certainly not to the same extent, about interactions, so it is a much more precise tool and it allows the breeder to gain in efficiencies.

Lord Rathcavan

360. From disease resistance to antibiotic resistance. One of the public concerns of potential damage to health from GM crops has been the use of antibiotic resistant marker genes. Is this antibiotic resistance in GM foods a genuine cause for concern? Is it your aim to phase out the use of such antibiotic resistance marker genes and, if so, by when?

(Dr Waters) Perhaps just to put antibiotic resistance markers into a broader context, the marker genes are an essential tool for the molecular biologist because they allow him to select out individual plants which have received the gene of interest—so that the marker genes are actually just a tag to allow the molecular biologist to quickly identify those plants which have acquired the trait of interest. Currently there is a very restrictive number of marker genes which are available. Antibiotic resistance marker genes are one example. Herbicide resistance is another example of a marker gene which could be used for this selection process, but the number of alternatives beyond those two examples is very limited indeed, and so companies have habitually been faced with the choice between antibiotic resistance markers and herbicide resistance markers. This, we recognise, has raised public concerns about the possibility that this could contribute to the important problem of antibiotic resistance in the broader sense. However, having said that, if one looks at it from a purely scientific point of view now, this question has been addressed by a lot of experts both in Europe and internationally. The question has been addressed by the FAO, the WHO, and it has been examined by the European Union scientific committees. It has been examined by regulatory authorities in Switzerland, the United States, Canada and Japan, and the overwhelming conclusion has been that, at least for those products which have been reviewed to date, the use of these antibiotic resistance markers does not represent significant risk either to human health or to the environment. These authorities came to this conclusion after consideration of the likelihood of the transfer of the gene from plant material into microbes, specifically in the gut, and the conclusion was that the likelihood of that happening is negligible. The assessment then went on to look at the possibility or the likelihood that this could somehow compromise the therapeutic value of antibiotics and the conclusion

there again was that the likelihood was negligible on the grounds that these genes are already present in high frequencies in natural populations and, indeed, the genes were taken from natural populations in the first place.

Chairman

361. Nevertheless, the concern persists. Is there any prospect of any marker genes being developed that would not have these disadvantages in the future or any possibility of removing the marker genes before they come to the commercial release stage?

(Dr Waters) We have recognised the public concern and we have accelerated our efforts, at least internally in Monsanto, to develop alternative methods. There are methods which have worked under experimental conditions, such as the Cre/lox system which, in theory at least, is able to remove genes once they have been inserted into the plants. There are also alternative selective marker systems which have been developed, but they are not yet at the point where they are a viable alternative to antibiotic resistance markers. Our intent is to move towards these alternative systems as much as possible, once they have been developed to the point where they are a viable alternative and we would de-emphasise the use of antibiotic resistance markers as these alternatives become available.

Lord Rathcavan

362. You have said that the opportunity for antibiotic resistance to enter the food chain is not impossible, you said it is negligible, so there is a very remote possibility for that to happen, if I interpret what you were saying correctly.

(Dr Waters) The experts who have looked at this have used classical risk analysis, which involves assessing the likelihood of an event occurring and then, secondly, if it were to occur, what the consequences would be, and in both cases the conclusion was that the risk would be negligible and, therefore, the combination of the two unlikely events is an extremely unlikely event. One can never say, though, that the risk is zero, but certainly taking into account all of the available scientific information, the risk is considered to be negligible.

(Dr Baker) Or vanishingly small, I think is the term used in the United Kingdom, whatever that means.

Chairman

363. Can I ask your views about the problem of the genes escaping from crops to relatives of the crop in the wild, and how big a problem is it, in your view. How big a risk is it and how should it best be dealt with? Is it dealt with best by segregation and refuge areas or is there a possibility of producing crops that do not reproduce with a male sterile or only female crops? Is that the best solution? Also what happens if gene stacking takes place, that is to say, weeds build up a resistance to more than one herbicide as a result of out-crossing or back-crossing? Is that a big problem

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and how should that be dealt with, as you see it? Finally, do you have any products under development currently which are resistant to more than one herbicide?

(Dr Waters) There is a series of questions there and I will try and cover them in my response. The notion of genes escaping is probably a misunderstanding of what actually occurs today, because genes are never contained within a plant, but genes are flowing as part of pollen grains in nature right now, so every time a pollen grain is shed from a plant, then tens of thousands of genes are shed into nature. Gene movement is a natural phenomenon and, therefore, one has to focus in, on a case-by-case basis, looking at each particular crop and each particular trait which is introduced into the crop to try and assess whether that gene movement has any consequences or not. Taking oil-seed rape as an example; oil-seed rape is known to be an out-crossing crop. Its pollen is shed and pollen can move to nearby crops or it can move to a related species and hybridisation can take place, and this has been happening for centuries, so the more critical question is whether the fact that you have introduced a new trait does somehow confer a selective advantage to those species which receive the gene through cross-pollination. In the case of a herbicide resistance trait, perhaps to use the Roundup Ready trait as an example, we have looked at the possibility of whether by acquiring the trait, related species and indeed related plants from the crop itself would have some selective advantage which would allow them to prosper at the expense of surrounding plants. The conclusion from those studies is that the trait itself does not change the morphological characteristics or the fitness characteristics of the plants, or of any plants receiving the trait through cross-pollination, in the absence of a treatment with the herbicide and there is no change in the fitness characteristics of these plants. However, if one applies the selective agent, in this case Roundup herbicide, then clearly those plants would survive at the expense of those surrounding plants which do not have the herbicide tolerance characteristic. Clearly in a natural situation, one would not be spraying a herbicide in that situation. The area of interest is more in the agricultural fields where farmers may have to deal with plants which have acquired the herbicide resistance gene through hybridisation. We have examined the consequences of this and, in most cases, the conclusion has been that the current methods of control would be adequate to control those plants. For instance, what farmers do today to control weeds is essentially to use cultivation methods or selective specific herbicides, and both of these techniques would be equally effective on plants with and without the herbicide resistance trait. That would also be valid for plants which have acquired two herbicide resistance traits through hybridisation, so having acquired two traits would not affect their ability to be controlled by cultivation, or the use of selective herbicides. So in that specific case of oil-seed rape, containing a herbicide tolerance trait, we do not believe that out-crossing is going to result in adverse environmental effects. It may change the way that farmers control weeds today and so there may be some

agricultural implications, but, as I have said, in most cases there would not be a change in agricultural practices, but in certain specific cases, farmers may have to change, for example, their rotation practices or their weed control practices in order to accommodate the transfer of the gene to a related species.

364. And male-sterile or all-female crops?

(Dr Waters) There has been some work on chloroplast transformation so that genes would be inherited by the maternal part of the plant rather than the paternal part, which would prevent transfer of the gene through pollen flow, but would still leave open the possibility of hybridisation in the other direction, that is, pollination by a related species so that the progeny could also contain the gene which has been introduced. I am not particularly familiar with these techniques, but that is something which one could perhaps explore as a means of at least reducing the flow of transgenes away from the crop.

365. Are you developing products which are resistant to more than one herbicide?

(Dr Waters) We are developing products where different traits are combined; for instance, insect-protected traits and herbicide resistance traits, but, to my knowledge, we have not developed products which combine two different herbicide resistance traits.

Lord Jopling

366. We seem to be moving towards an ever-diminishing number of large seed companies and given the fact that they are likely to have very few GM varieties available, it means that there could be an ever-decreasing variety of crops used in agriculture. Are you concerned about this and moves towards monoculture? Are you concerned about the effect of a crop failure and to what extent are you covered by insurance as a company for some horror situation which might emerge from the introduction of genetically manipulated varieties?

(Dr Baker) You have suggested that there would be a movement towards monoculture, but I think in the last few years there has been a focus on a certain number of crops already with or without biotechnology. Obviously one of the reasons for that is because, as breeders select varieties, they are selected for certain traits which are better than others. Again this is somewhat peering into the future, referring to your earlier question, but we can imagine that some of those older varieties which have been used, if they are given these newer traits through biotechnology, will come back into use again. So in many ways it is possible that we would get a trend away from the existing trend towards monocultures, which answers your second question about crop failures. In terms of insurance against crop failure, we, as most other companies, accept civil liability in any case with respect to what may go wrong with our crops and we are required to take full responsibility for that. In terms of special insurance, to my knowledge, we do not have any special insurance in the sense that we already take responsibility and coverage for anything we do as a company.

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367. So if something went wrong with a GM variety and you got sued, you would be covered by your existing insurance?

(Dr Baker) We have coverage, yes.

368. And you believe you would be fully covered, do you?

(Dr Baker) This I would have to put to our lawyers, but we believe that we are adequately covered.

Chairman

369. Your second paper sets out the very considerable input savings that appear to be made as a result of growing GM crops, but there is a very wide degree of scepticism in this country regarding those claims insofar as what we have heard from the evidence we have taken, and I would like to quote to you something from a paper which has been produced in evidence to us by English Nature, which is a statutory body which advises the Government. They say here, "There is no evidence that the new crop management system associated with growing genetically modified herbicide tolerant crops will reduce overall herbicide use in the countryside. Even though GMHT crops may require fewer herbicide applications, there will probably be a large increase in the total area being sprayed because certain broad spectrum herbicides would be used for the first time on growing crops, like sugar beet and oil-seed rape, which were previously damaged by herbicides", and they end by arguing that, "There would be an increase in the use of broad spectrum herbicides". What do you say to that argument?

(Dr Baker) Let me start with an answer and I think maybe there is a technical response also. The first thing to say to that comment is that, based on our customers' experience, that is to say farmers mainly in the Americas, North and South America and Australia, purchase these products because of a benefit for the farmer. Now, where does the benefit come from? It comes from, amongst other things, a reduction in the input costs and a reduction in chemical use. Let me put it another way: that if there were an increase in costs for the use of herbicides or indeed any other products such as insecticides, we would probably not sell the seeds. Therefore, I think the evidence from the farmer is that he buys them primarily because of the reduced overall cost. That is one of the things we document in our second submission. In terms of the overall increase in herbicide use, maybe, Dr Waters, you can comment on that. I think the same argument goes, that there is no logic in a product which increases the amount of chemical use on a more expensive seed as there would be no reason to buy the product in the first place.

(Dr Waters) I think the comment was that there would be an increase in herbicide use and I think they (English Nature) mention that, as an example, there would be an increase in the use of broad spectrum herbicides in sugar beet. The latter statement is true, since we would be promoting the substitution of the herbicides which are used currently by Roundup which

is a broad spectrum herbicide. If one looks at weed control practices today in sugar beet, virtually every sugar beet farmer applies herbicides because competition from weeds early on in the development of the crop has a significant effect on yields and, therefore, farmers are currently making (usually) three trips across the fields and applying a mixture of different non-selective herbicides. In the case of tolerance to a broad spectrum herbicide, farmers can now substitute that mixture of selective herbicides by one single broad spectrum herbicide, so there will be an increase in the amount of broad spectrum herbicide used, but it will be at the expense of the herbicides which are used currently. In this specific example, this new approach provides considerable benefits in terms of the reduction in the amount of active ingredient which is applied to the sugar beet fields, but also as well as from the benefits which spin off from that, such as the characteristics of the products which are used and other potential benefits, like the possibilities to move to conservation tillage practices, so one has to look at the current systems in comparison with these new systems in a broader context.

Lord Gallacher

370. On the question of monitoring, can we return to the proposed draft revision of Directive 90/220 where in that draft revision of the Directive, the Commission raise the question of monitoring for environmental impact after commercial approval has been given. What is your view of the feasibility of such a programme and, secondly, the desirability of such monitoring?

(Dr Waters) I think to some extent we have addressed this question previously, but perhaps just to summarise that, I think post-marketing monitoring is certainly no substitute for a thorough risk assessment prior to the launching of the products. That risk assessment involves addressing, to the extent that it is possible, future developments and future generations. Secondly, we are certainly supportive of post-marketing surveillance programmes. This would be part of the standard product stewardship programme that we have for all new products. In fact, for the products which are currently going through the regulatory process prior to the introduction of the 90/220 revisions, we are actually including surveillance proposals in our regulatory submissions, so we are voluntarily taking the step of ensuring that correct surveillance networks are in place which would allow feedback in the event of an adverse effect. Monitoring, in my mind, has a different connotation. Monitoring is more active; it is actually going out and measuring things. I am certainly supportive of that in the event that a specific risk has been identified and it is clear what the objectives of such monitoring should be. If a potential risk has been identified, then one should develop scientific protocols to understand what that risk could be, how that risk would be manifested and how one could measure the risk. So my response on monitoring would be that this should be restricted to those products where a specific risk has been

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[Lord Gallacher *Contd*]

identified rather than monitoring for the sake of collecting information.

Lord Jopling

371. Whilst I would not wish to put your company in the same league as the tobacco companies whose monitoring of the effect of tobacco on human health gives rise to certain questions, would you not agree that it would be better that monitoring be done by an outside body and not by the companies themselves?

(*Dr Waters*) Well, one example I can think of is in France, where a committee has been set up as well as at the European level; a group of experts has been established to look at the question of insect resistance management in insect-protected maize, for example, and that committee is composed of national experts. Those experts have devised the monitoring protocols and they supervise the implementation of those protocols. Certainly when it comes to monitoring, there is something to be said for having independent scientists doing that. In the case of the surveillance, clearly companies who develop the products are best placed to collect information on any unexpected events which take place in the marketplace, simply because we have the connections to our customers and to the distribution chain, although, having said that, there are technical institutes in most countries which are also a part of that network, so there is also a means for independent feedback as part of the surveillance programmes.

(*Miss Foster*) In terms of food safety, you will probably be aware that the Advisory Committee on Novel Foods and Processes has already begun to address the issue of monitoring and I think in terms of public perception, it would be preferable for it to be done by a respected independent expert body, but of course we would wish to co-operate in whatever way was thought necessary.

Chairman

372. Could I raise briefly the question of segregation. Can European consumers expect in future to be able to source non-GM soya from the United States or not? What, as you see it, is the likely progress of segregation in the United States in that area? Are we correct to assume that originally you were not in favour of the United States soya producers segregating GM from their non-GM crops?

(*Dr Baker*) Maybe I will answer the second question first as to whether we were in favour of

something or not. I do not think we are in a position to be in favour of segregation because we have no control over that; we sell the seeds to the farmers. It is probably true to say that we underestimated the emotional impact here of the fact that it was not able to be done. Nevertheless, your first question was whether it will be available in the future. My understanding is that segregated crops are available now, provided one places an order for them. They are on the market and, I would suggest, always have been, but of course it depends on the company requiring the product actually placing the order for the crop itself.

(*Miss Foster*) What we are seeing in the United Kingdom, though, is that the market is now working where consumer demand for non-GM sources has developed, and this is something that the retailers and the manufacturers are seeking to satisfy and they are doing this by identity preserved sources. If we look at, for example, the recent announcement by Iceland Frozen Foods that their own-brand products from the 1st May will not contain GM sources, that does illustrate that the market mechanisms can and do work if there is consumer demand. Also there has to be a determination to work this all the way through the chain from the harvest right through to the final product.

373. Well, thank you very much. I think that is probably all we have time for. The Committee is extremely grateful to you for having come to give evidence to us. It has been quite a long session for us, but then of course you are an exceptionally important company in this area. Do you appreciate your significance in this area and the significant impact that you can have on whether genetic modification in agriculture is accepted broadly in this country and in Europe and that much may depend on how you conduct yourselves?

(*Dr Baker*) We accept fully that responsibility as a company and we appreciate your interest in hearing our views on many of the subjects which you have raised which relate to questions of public concern. In terms of our importance, I think we think of it slightly differently in that we have many competitors in the field and I do not think we necessarily regard ourselves as being in the lead, but we do appreciate our role in this new developing area of what is called life sciences and being one of the key players in it.

374. Well, thank you, Dr Baker, Dr Waters and Miss Foster, very much indeed for having come here.

(*Dr Baker*) Thank you, my Lord Chairman.

WEDNESDAY 8 JULY 1998

Present:

Gallacher, L.
Moran, L.
Rathcavan, L.
Reay, L. (Chairman)

Redesdale, L.
Wade of Chorlton, L.
Willoughby de Broke, L.

Letter from the United States Department of Agriculture

Thank you for the opportunity to comment on the EU's regulatory system for genetically modified foods. In fact, our biotechnology industry has expressed considerable frustration at the cumbersome and unpredictable procedures in the EU, and at the length of time it takes for the EU to review and approve products for commercialisation. This year, over \$200 million in US exports of corn to Spain and Portugal are jeopardised, because—after more than two years and multiple positive safety assessments—the approval process for three new corn varieties is still not complete. We hope that planned revisions to Directive 90/220 and the Novel Foods Regulation will simplify, shorten, and add more certainty and transparency to the EU's review and approval process. Following are some specific concerns:

- *EU time frame for approval is too long*: whereas the review process for products derived from biotechnology in the US, Japan, and Canada normally lasts less than a year, in the EU it frequently lasts more than two years. This difference in time frames is not the result of more exhaustive scientific review: in all countries there is a high degree of commonality in the data sets and criteria used to conduct assessments. Rather, it is the politicisation of the EU approval process that has caused lengthy, unnecessary delays.
- *Politicisation of the EU approval system*: the overlay of member-state voting on top of the scientific review process causes considerable delays in the approval of notifications—and could possibly cause rejections—which are unrelated to the scientific criteria of safety to humans and the environment. In the US, regulatory agencies conduct scientific reviews and come to independent decisions.
- *Lack of transparency/predictability*: The private sector needs to have a predictable and transparent process to make informed decisions about when to notify their genetically modified product. A number of *ad hoc* changes have been made to the procedure laid out in Directive 90/220, so that business has more difficulty anticipating EU regulatory needs and planning the marketing of their products. Predictability and transparency also has an important international dimension, especially for crops. Companies lose the ability to co-ordinate approvals and plantings in different countries, increasing the risk that a crop will be harvested in a country which historically exports to the EU before that crop is approved for marketing in the EU. For example, Directive 90/220 does not require scientific review by the Commission, yet the Commission recently conducted such a review for four GMO varieties of corn and soybean without giving the companies any prior warning that this would be part of the process. US regulatory agencies also can utilise scientific expert committees during the review process. However, they attempt to predict when such committees will need to be convened and they have defined procedures and timeframes for utilising such committees. In this way, companies are better able to anticipate how long the entire review process will take.

I am attaching for your information US comments submitted to the WTO on the proposed Commission Regulation concerning labelling of Roundup Ready soybeans and Bt corn (EU notification 97.766) as well as some information on the US regulatory process for commercialisation of products of biotechnology.

We would be happy to provide additional information that the Committee might request.

Lloyd Harbert

Director

ADDRESS OF CONTACT POINT

Re: G/TBT Notification 97.766. Commission Regulation (EC) concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

DEAR

We appreciate the opportunity to review and comment on the above referenced regulation proposed by the Commission of the European Community (Commission). The regulation has been reviewed by scientists in a number of United States (US) federal agencies. The following comments reflect reviews by scientists at the

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Foreign Agricultural Service of US Department of Agriculture (USDA), the Animal Plant Health and Inspection Service of USDA, the Centre for Food Safety and Applied Nutrition of the US Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).

We would like to offer several comments for your consideration. These comments are based on the experience in the US with foods and food ingredients derived from sources that have been modified through recombinant DNA techniques and on the scientific expertise and experience of the technical experts in the above listed US federal agencies.

Commission Proposed Regulation and US Policy

The regulation proposed by the Commission defines when labeling would be required for foods and food ingredients produced from “genetically modified” maize and “genetically modified” soya beans. According to the proposed regulation, the presence in foods and food ingredients of DNA resulting from genetic modification would render that food no longer equivalent to its conventional counterpart and therefore labeling would be required. If the DNA has been destroyed during processing, the food would be considered equivalent as long as there is no protein present as a result of genetic modification. When labeling would be required under the proposed regulation, the words “produced from genetically modified soya” or “produced from genetically modified maize” should appear on the ingredient list or on the labeling of the food. If it is not definitively known if a food or food ingredient is produced from, or contains, genetically modified soya beans or maize, the words “may contain” or “may have been produced from” would be used.

Current US policy does not require mandatory labeling of *all* genetically engineered (modified) foods and food ingredients or additives solely because of their means of production (i.e., because they are genetically engineered). Likewise, the US has not required labelling for other methods of plant breeding such as chemical—or radiation—induced mutagenesis, somaclonal variation, or cell culture. For example, varieties of sunflower and safflower have been developed through conventional mutagenesis to yield high levels of oleic acid. The oils from these varieties are labelled as “high oleic sunflower oil” or “high oleic safflower oil”, respectively, the method of mutagenesis used to select the new varieties is not required to be included on the label. Similarly, oil derived from genetically engineered canola plants that have high levels of laurate is called “laurate canola”, and the oil from genetically modified soybean plants modified to express high oleic acid content is called “high oleic soybean oil.” Again, the method of development is not required to be disclosed on the label.

The US does not believe that information based solely on the method of production would convey any meaningful information to consumers. As is the case for foods produced by other technologies, the US does require labeling of foods produced through modern biotechnology to denote significant changes in a food with respect to composition (e.g., nutritional content) storage, preparation or usage, and the presence of a new allergen. The US encourages industry to disseminate information concerning genetically engineered foods, but does not believe that labelling is the most practical way to provide access to such information, particularly for comingled commodities and processed foods containing material from different sources. The costs of applying such labelling would ultimately be borne by the consumer regardless of the level of their concern without providing any greater assurances of safety.

Labeling Requirements

The proposed regulation states the necessity of establishing clear labeling rules that can be controlled on a “reliable, readily, repeatable practicable basis” and that common scientifically validated testing methods should be developed. In the proposed regulation, the Commission has stated that the labeling requirements should not be overly burdensome. The approach proposed in the regulation would be reconsidered as new scientific information is developed. Although we agree with these overall goals, we believe a number of issues addressed in the proposed regulation have a questionable scientific basis and are ambiguous and impractical.

The proposed regulation considers the presence of DNA resulting from genetic modification to be sufficient for identifying a food as no longer equivalent to an existing food, using the approach taken in the European Parliament and Council Regulation on Novel Foods and Novel Food Ingredients under which a food would not be equivalent if its composition, nutritional value or intended use would be different from existing food. (see Paragraph 9 of proposed regulation). In doing so, a questionable link is made in the proposed regulations between labeling for scientifically based health reasons such as composition, nutritional value or nutritional effects and labeling that requires scientific methodologies be used purely for monitoring purposes. The presence of DNA “from genetic modification” does not by itself result in food no longer being equivalent to its conventional counterpart as described in paragraph 9 of the proposed regulation. The logical extension to this approach would be that any changes in DNA due to genetic manipulation (e.g., chemical mutagenesis, somaclonal variation) would result in food no longer being equivalent. The proposed regulation appears in reality to be using the presence of DNA from genetic modification for monitoring purposes to determine whether a food or food ingredient is in some way made from a genetically modified component.

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There are a number of practical questions that are raised by the proposal as well. The proposal does not address if and when tests would be required to determine if DNA (or protein) from genetic modification is present. It does not stipulate a standard test that would be used or the limits of detection for these tests. For example, under the proposal, a food would not have to be labeled if DNA has been destroyed by processing but the proposed regulation does not stipulate a limit of detection for determining whether DNA would be considered to be present in that food.

There are a growing number of extremely sensitive tests for both protein and DNA. However, these tests are used primarily for research purposes and are not time efficient and are costly. In addition, in order to test for the presence of DNA or protein from genetic modification, it will be necessary to know what specific piece of DNA, or which protein, is being monitored. The variety and number of traits that are introduced into crops via modern biotechnology is increasing. As these agriculture biotechnology products enter the market, the complexity and difficulty of such testing will be greatly magnified. The end result is that most products would be labeled as "may contain" or "may be produced from" genetically modified soya or maize. As stated earlier in these comments, we question the relevance of information based purely on process as giving the consumer any meaningful information.

The proposal also does not describe how the regulation will be enforced and how uniformity in this enforcement will be maintained among the member states. This lack of precise explanation could result in different levels of enforcement and specificity in any required monitoring. Such a lack of clarity will place an undue burden on producers when attempting to comply with the regulation.

We urge the Commission to take the above points into account when finalising the proposed regulation. Without addressing these issues, we believe it will be extremely difficult for the Commission to implement a regulation that is scientifically based, predictable and transparent.

US REGULATION OF PRODUCTS DERIVED FROM BIOTECHNOLOGY

US authorities regulate bioengineered products based on a determination of their safety to humans and the environment. In the United States, four federal agencies are responsible for ensuring the safety of bioengineered plants, animals, seafood, microorganisms, and the products obtained from them:

- USDA/Animal Plant Health Inspection Service (APHIS)
- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- USDA/Food Safety Inspection Service (FSIS)

Depending on the properties and intended use of a bioengineered plant, animal, seafood, microorganism, or product, one or more of these agencies is responsible for regulation or approval:

- *APHIS* issues a "determination of non-regulated status" for the commercialization of bioengineered plants and pathogenic plant microorganisms that meet its safety criteria, with a particular focus on their environmental release (planting). In addition, APHIS issues permits and acknowledges notifications for field testing, importation, and inter-state movement of genetically engineered organisms. USDA has authority to prevent the introduction and dissemination of plant pests under the Federal Plant Pest Act and the Plant Quarantine Act.
- *EPA* approves bioengineered pesticides, bioengineered plants with pesticidal characteristics, and reviews "integeneric microorganisms" (formed by combining genetic material from microorganisms in different taxonomic genera) prior to activities related to commercialization. EPA focuses on food safety (tolerance levels) and the environment (target and non-target organisms). EPA regulates *pesticides* under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Generally, before a pesticide may be sold, distributed or used in the United States, it must be registered under FIFRA. Under FFDCA, EPA is responsible for setting tolerances or exemptions from the requirement of a tolerance for pesticide residues in foods. EPA regulates *integeneric microorganisms* under Section 5 of the Toxic Substances Control Act (TSCA). Before a new microorganism can be manufactured processed or imported for a commercial purpose, a notice must be submitted to EPA.
- *FDA* regulates foods (except meat and poultry products), including fruits, vegetables, grains, fish, and shellfish, milk, and substances added to food such as vegetable oils, flavors, sweeteners, spices, and enzymes., Food additives, color additives, and new animal drugs require pre-market approval by FDA. FDA consultation is recommended for bioengineered foods. Additionally, FDA can take regulatory action against foods that are adulterated or improperly labeled. A food is considered adulterated, and unlawful, if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health or a naturally occurring substance at a level that is ordinarily injurious.

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— FSIS approves the slaughter of research animals for meat for human consumption.

The timeframe for approval of a bioengineered product depends on which agencies are regulating or being consulted. This normally ranges between 2 and 12 months, with an average product approval time of 6-8 months. APHIS expedites a determination of non-regulated status for organisms which are largely similar to organisms already granted such status. EPA decisions are normally made within 12 months from receipt of the application, but take 60 to 90 days in the case of applications for R&D and commercial use of intergeneric micro-organisms. However, product approval can be delayed if the application is incomplete or if more data is required to conclude the safety assessment.

BACKGROUND

Since 1990, more than 25 agricultural biotechnology products have successfully progressed through the US regulatory system to commercialization into the marketplace. Some of these products are very familiar. For example, in 1990, FDA approved the commercial use of chymosin (rennet) produced from bacteria for use in making cheese and other dairy products. In 1994, the "flavr savr" tomato was first commercialized. In 1996, EPA approved the use of a genetically engineered *Bacillus thuringiensis*, a commonly used microbial pesticide. Other products approved in the United States represent technological advances in producing crops with new insect and disease resistances, other improved agronomic characteristics, and improved processing characteristics. In the last three years, the United States approved for commercial use insect resistant corn, cotton and potato; herbicide tolerant canola, cotton, soybeans and corn; delayed ripening tomatoes; and canola with a different oil composition.

In the 1970s, the United States regulatory framework for agricultural biotechnology products initially focused on contained testing in laboratories and greenhouses with the publication of the "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules" (NIH guidelines). As products moved from basic research and development to field testing and eventual commercial release, the United States government published the "Co-ordinated Framework for Regulation of Biotechnology" in 1986 to explain how the federal agencies would regulate research as well as commercialization.

The Co-ordinated Framework takes a "vertical" or sectoral approach to the regulation of biotechnology products, including agricultural biotechnology products. Under this approach, biotechnology products are regulated, using existing statutes, as are other similar products. For example, biotechnology products that are food would be regulated by the Food and Drug Administration (FDA) under the Food Drug and Cosmetic Act (FFDCA), biotechnology products that are pesticides would be regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and FFDCA, and plant pests would be regulated by the United States Department of Agriculture (USDA) under the Plant Pest Act and the Plant Quarantine Act. In the Co-ordinated Framework, USDA, EPA, and FDA are identified as the primary regulatory agencies responsible for products of agricultural biotechnology. Under this framework, some products may be regulated by all three agencies and some may be regulated by one or two agencies.

The basis of the Co-ordinated Framework was the belief that use of existing health and safety laws provided more immediate regulatory protection and certainty than was possible with new legislation specific to biotechnology. Moreover, there did not appear to be an alternative, unitary statutory approach because the broad spectrum of products obtained through genetic engineering cuts across many different types of products regulated by different agencies. The US Government believes that the new techniques of genetic engineering are an extension of biotechnology in general and, thus, new products developed through these techniques are extensions of existing product classes.

FOR MORE INFORMATION

Detailed descriptions of procedures and contact information related to biotechnology can be obtained from the following US government websites:

APHIS: <http://www.aphis.usda.gov/oa/new/ab.html>

EPA: <http://www.epa.gov/opptintr/biotech/index.html> (for TSCA)

<http://www.epa.gov/pesticides/activity.htm#bio> (for biopesticides)

FDA: <http://vm.cfsan.fda.gov/~lrd/biopolcy.html>

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Examination of witness

MR TIMOTHY GALVIN, Associate Administrator, Foreign Agricultural Service, United States Department of Agriculture, examined.

Chairman

375. Mr Galvin, good morning and welcome to the Sub-Committee. I start by thanking you very much for having taken the trouble to come all the way from the United States to give evidence and help us in our enquiry into genetic modification in agriculture with particular reference to regulation. We have just received from you written answers to some of the questions that we put to your department relating to the practices in the United States. Having had a quick glance at the document, it appears to be a very full reply to our questions. I believe that initially you had difficulty in answering these questions due to the fact that other departments of state needed to be consulted. If that is the case these answers have been provided with great speed. We are extremely grateful that you have been able to do this. Perhaps you would thank on our behalf all those involved. I understand that you propose to begin by making a brief introductory statement. If that is the case, I give you the floor straight away.

(*Mr Galvin*) My Lord Chairman and members of the Sub-Committee, I appreciate this opportunity to present the views of the US Department of Agriculture with respect to the regulation of genetic modification in agriculture. As a former staff member of the US Congress for nearly 17 years, I consider it a special privilege to be here this morning. In advance of today's hearing the Sub-Committee posed a number of questions to the US Department of Agriculture. Those questions sought more information about the details of the US system for regulating genetically modified organisms as well as our views on the European Union's regulation of those products. Because the US regulatory system involves three separate federal agencies—the Animal and Plant Health Inspection Service, the Environmental Protection Agency and the Food and Drug Administration - we consulted with those agencies in answering the questions relating to the specifics of the US regulatory regime. As has been indicated, I am providing those answers to the Sub-Committee this morning. In addition, the Sub-Committee asked us to review and comment upon a draft paper that has been prepared for the Sub-Committee that analyses the US regulatory system. This is a matter that also requires input from our three regulatory agencies. They have asked for additional time to prepare a response. With your permission, our reaction to that paper will be provided next week. The Sub-Committee's effort to examine the regulation of agricultural biotechnology is one that we welcome and are eager to support. We fully recognise that the EU has the right to put in place its own system for governing the approval and marketing of genetically modified products. Our chief concern is that such a system be characterised by certainty, timeliness and an adherence to those science-based standards that are necessary to ensure the protection of consumers and the environment. Similarly, we are concerned that any policy developed for the labelling of these products be practical and not constitute a barrier to trade. For our

part, we in the US Government have been engaged with EU officials on a bilateral basis to share information and foster co-operation in this area. We have also been active participants in the Trans-Atlantic Business Dialogue (TABD) and are encouraged by progress made under the TABD to improve the regulatory systems on both sides by exploring common regulatory approaches, such as requiring similar data submissions. In our view, there is much at stake in achieving an improved means to regulate biotechnology worldwide. Clearly, the acreage devoted to genetically modified varieties is increasing rapidly, as is the number of varieties being offered to the marketplace, with obvious implications for trade and commerce in general. More importantly, these products if regulated properly offer significant benefits in the form of reduced chemical use, improved yields, lower production costs and enhanced qualities for consumers and other end users. I appreciate the opportunity to be here and look forward to answering your questions.

Lord Gallacher

376. Can you explain to the Sub-Committee what you see as the fundamental difference between the EC approach to biotechnology regulation and that undertaken in the US?

A. In general, the key difference is that in the US our regulatory system is well established. From the standpoint of the regulated community it is viewed as offering a reasonable degree of certainty with respect to requirements and procedures. By contrast, the EU regulatory system is perceived as still evolving. Therefore, it is viewed as uncertain and subject to changing procedures that perhaps are not always driven by science-based requirements to ensure safety of the regulated products. Currently, the issue of uncertainty as it relates to product labelling and approval probably gives rise to the greatest difference.

Chairman

377. Do you think that in Europe we look more at wider environmental issues than in the United States?

A. I do not believe so. Frankly, I believe that there is great interest in both the US and EU in looking at the environmental side of the equation and trying to provide reassurance that these products are safe. I do not perceive that there is a greater concern or awareness in the EU than in the US. We are fortunate in the sense that in the US we went through this whole procedure a decade ago. The procedures are well accepted and well known by the regulated community as well as by consumers groups that closely follow the process.

378. Is the situation in the US fairly stable? There is no pressure to change the regulatory system in any way to take into account considerations that hitherto have not been taken into account?

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[Continued]

[Chairman *Contd*]

A. More recently, there was a request by some consumer groups for the labelling of these products. There are some in the US who believe that we should do more to regulate these products or label them, but they tend to represent a minority. The overwhelming majority of the public accepts the procedures that we have in place. Part of the reason for that is that from the very start our process involved a period of public comment and review. Even to this day as specific products are reviewed and approved they are noted in our federal register so that there is an awareness on the part of those following this issue as to exactly what steps the federal agencies have taken to approve these products.

Lord Redesdale

379. You referred to labelling. In supermarkets in the United Kingdom every genetically modified product is labelled. Are you saying that in the US some products are not labelled as such?

A. That is correct.

380. Consumers are not aware that they are eating genetically modified products?

A. Not in each and every case, but they are aware that these products have been approved and are available in the marketplace.

Lord Wade of Chorlton

381. You are critical in your paper of the EC approval system. What changes would the US like to see take place?

A. The issue comes down to certainty, timeliness and transparency in the process. We view the EU system as still evolving. Frankly, we are confused as to which authority is controlling this area. Is it Directive 90/220 EEC or the Novel Food Regulations, and so on? We do not know exactly what procedures the various companies must follow in getting products approved. That uncertainty is now complicated by the new proposal on labelling because the practical aspects of that policy are not clear to us. For example, it is not clear what testing will be required or whether these commodities have to be identity preserved all the way through the process to the final consumer.

382. In the US, who assesses a product before it is allowed into the marketplace? What issues are examined? Are scientific committees consulted?

A. It is science-based. The Department of Agriculture examines these products to determine their likely impact on other plants or animal species. We review products for safety to agriculture. The Environmental Protection Agency looks at the impact of these products on the environment generally, especially since the EPA also regulates pesticide use. Many of these products are in some way related either to pesticide use or have inherent qualities that allow them to combat certain pests. The Food and Drug Administration, however, reviews these products to make sure that in the end they are safe to any consumers who may eat them.

383. Clearly, in the United States the public has tremendous confidence in the system that the US Government operates in terms of food. At the same time, it has turned out to be very effective in that the public has been given warnings about certain foods which have been quickly withdrawn from the market. In Europe the experience is very different. There is considerable concern about it. Very often, what governments say is the opposite of what people believe. How would you tackle that on a European basis? Would you like to see a more European-based committee or group that considered all of these issues? You talk about certainty, but how do you take the first steps in ensuring that there is certainty and that consumers can have confidence that what the body says is correct?

A. That takes us back to the first steps that the US took when it put its policy in place. We went to the public and offered a proposal for the regulation of these products. That proposal was subject to public comment and review. That transparency in the system has been ongoing ever since, in the sense that we have scientific committees that meet periodically to review issues that come up. We also issue public notices on products that are approved. I believe that in the view of those members of the public who follow this issue there is a sense that we have not hidden anything and everything is on the table for consideration. With all due respect, I suggest that that is an important way of moving ahead and building public confidence in this area. I have seen some of the polling data both in the US and Europe with regard to consumer attitudes towards biotechnology. From what I have seen, it appears that the difference between the attitudes in the US and those in many European countries are not that great. In general, it appears that about two-thirds of the public endorse the idea of biotechnology, at least from the survey data that I have seen. I am happy to share that with the Sub-Committee this morning. For example, if you ask consumers even in Europe how they rank the various threats to public health at the very top is bacteriological contamination and biotechnology ranks at about no.8, just ahead of food colouring.

Chairman

384. In the paper that we received from you a criticism was made of the Commission's use of review by scientific committees, particularly in the case of corn. Do you recall that and, if so, would you care to comment on it?

A. It does ring a bell. We are not at all opposed to scientific review in the case of these products. What we were concerned about in this specific instance was the fact that this particular scientific review was introduced very late in the process after the same products had already been reviewed at the Member State level and then by the Commission itself. Therefore, our concern was that it represented a change in procedure very late in the game that added another scientific review to the process.

385. You are also critical of the EC regulatory system on the ground of politicisation. Can you explain what you mean by that?

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[Continued]

[Chairman *Contd*]

A. Perhaps the best recent example of that is the situation that we face in France where two of our corn products still await final approval. These products were reviewed by France more than two years ago and then sent to the Commission. The Commission approved those products in April after that extensive review and re-review. They were then sent back to France for final technical approval which should have been almost a formality. Although these products have received clearance by the Commission, France withheld that final step of approval, even though French officials assured us that there were no concerns about science or consumer safety; rather, there was concern about public opinion. Therefore, France said that it would be holding a so-called consensus conference. That took place about three weeks ago. I believe that that will be the final step before they decide whether or not to let these products go.

386. Is the problem in Europe that there are consumer concerns which are different in various Member States which make themselves felt through government action at different stages in the process? This is not a problem that you have in the United States, though I understand from what you say that perhaps you had such a problem at one time. How can governments avoid taking account of such public opinion?

A. I recognise and appreciate the difficulty in Europe of trying to get the approval of 15 different Member States. Frankly, that is not a situation we face in the US. We do not have to go to any of our 50 states to get approval for these products. In that respect we are very fortunate. In terms of increasing public confidence in whatever approval system is put in place, we would encourage those concerned to take additional steps to increase the transparency of the process or invite consumer and public comment on the procedure so that the public has greater confidence in the system.

Lord Rathcavan

387. Could you deal in more detail with your labelling philosophy? The FDA state that the "Food, Drug and Cosmetic Act does not require disclosure in labelling of information solely on the basis of consumer desire to know." Do you consider that the consumer has the right to know? Perhaps you can illustrate this to us? I am not familiar with the practical example in the US of, say, how tomato paste is labelled if it is a 100 per cent GM product. In the case of certain products of which soya is a material ingredient, such as a pizza, does that also involve particular labelling?

A. First, perhaps I may explain the general policy that underlies the labelling requirements in the US. Labelling policy falls under the Federal Food, Drug and Cosmetic Act. Essentially, it requires that the labelling of products should be truthful and not misleading and it should include the common or usual name of the food. Perhaps more importantly, it requires labelling only if the end product is materially different in some respect. Our FDA has concluded after a careful review that inherently there is nothing in these genetically modified products that makes them materially different from their conventional counterparts. Therefore, we do not as a

general matter of policy require that these products be labelled. If however, in future there is a particular genetically modified product that is materially different from its conventional counterpart, it has to be labelled. Two specific examples: Our FDA has required that oil derived from genetically engineered canola plants that have high levels of laurate be labelled as "high laurate canola oil", and that oil from soybean plants modified to express high oleic acid content be labelled as "high oleic soybean oil". Both of these products are significantly different in composition and use than the conventional products. However, in neither case was the product label required to state that the oil was produced through genetic modification. Similar labelling requirements were imposed on specific sunflower and safflower varieties, even though those varieties were developed through conventional mutagenesis.

388. You do not label GM tomato paste?

A. It is just tomato paste. That is because the FDA has reviewed the product and concluded that the genetically modified version is not materially different from the conventional product.

Chairman

389. It is for the FDA to decide whether or not labelling is required?

A. Correct.

390. If, for example, an anti-freeze gene from a flounder or other fish is inserted into a plant would labelling be required?

A. That could be an example, but I would have to address that question to our FDA.

391. If there were a modification that reduced or increased fat content would that require labelling?

A. That sort of information is disclosed on the so-called nutritional panel on the side of the label. That covers fat and protein content but there is no specific mention of the fact that the product is genetically modified.

Lord Rathcavan

392. To return to the tomato paste, from our observation it is a different product compared to standard tomato paste. Although your FDA may say that it does not require labelling, in practice do manufacturers of that product choose to identify it as a different product—as a GM paste?

A. Our companies do not voluntarily disclose the fact that it is genetically modified. They are free to do that. We would support that sort of voluntary disclosure, but that is not something that the companies have chosen to do. However, if it is a flavour savour tomato, for example, they will sell that product with that sort of advertising so that people know it is a special tomato which is more shelf stable and so on. They do other things to advertise the fact that this tomato has special characteristics.

393. It is identified as a different product, not as a genetically modified product?

A. Correct.

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[Continued]

Lord Redesdale

394. Is that because such labelling would be detrimental to the sale of that product?

A. I do not know. You would have to put that question to the manufacturers. For whatever reason, they have not chosen to put that on the label. It is likely that they would do so if they thought there was great consumer concern in the US about whether or not the product had been genetically modified.

395. Has there been any campaigning against supermarkets who sell unlabelled genetically modified products?

A. There have been some but it is only a distinct minority who are in favour of this kind of labelling.

Lord Willoughby de Broke

396. Are there any consumer organisations represented on the regulatory agencies - the FDA, EPA and Food and Drug Administration - who monitor GM organisms?

A. No. The agencies are wholly comprised of government officials. We have scientific advisory committees. I do not have a list of their membership. I would be happy to provide that information for the record. It may be that some of the consumer groups have representatives on those committees. But the consumer groups are free to comment at various stages, even at the stage of developing regulations or as public notice is given that various products are approved or are about to be approved.

Chairman

397. Is it your view that a labelling requirement can constitute a barrier to trade?

A. It could depending on how it is constructed. For example, on the basis of the new labelling policy that has been issued by the EU it is not clear to us at this point what level of testing may be required. If the US sent a shipload of soybeans to Europe would each bin or hold of the ship have to be sampled individually or would there be one sample for the whole ship? It is not clear how intensive that sampling has to be, or what sampling methods will be sanctioned. Until all sorts of operational details are worked out we have concerns that this policy may constitute a barrier to trade.

Lord Willoughby de Broke

398. This brings us to the question of segregation. Our impression is that the US is opposed to segregation. Is that correct, or do you accept that segregation should be decided by consumer choice? Has the US Government made any attempt to prevent segregation either at home or abroad?

A. What we are opposed to in the US is mandatory segregation. We have not made any attempt to discourage segregation to the extent that if a seller wants voluntarily to segregate a commodity we are not opposed to it. If a seller can find a certain market niche by advertising a product as GMO-free or whatever he is free to do that. We would support that as a voluntary measure. But in the case of mandatory segregation the

issue for us is whether or not the end product is materially different. We have reviewed that issue very carefully in the US and have concluded that these products are not materially different from their conventional counterparts. We do not believe therefore that segregation is necessary. We also believe that on a broad scale segregation is impractical given the way that major commodities are produced in the US. Typically, our farmers harvest all their corn or soybeans together, put them in the same bins and move them to the same terminal elevators. It would be difficult and more costly if farmers segregated products according to whether or not they were conventional or genetically modified. However, increased segregation is occurring in the US but not as a result of whether or not the products are genetically modified; rather, it occurs because today farmers are more interested in producing certain commodities with special characteristics. In the case of corn, farmers are producing more higher oil, waxy or white corn that meet specific end-user requirements. That corn is then segregated and identity preserved in the marketplace. But typically it also commands a premium in the marketplace because it offers special characteristics. If a farmer is offered that premium for producing a different product then he is happy to segregate and give it the special handling and attention that it requires.

Chairman

399. We were able to meet informally members of the American Soybean Association who were over here earlier this week. We learnt of some of the potential difficulties of segregation that you describe. We also learnt of the likely prospect of all sorts of different types of genetically modified soya that may be produced in future which would make segregation essential. Therefore, genetically modified products could be a vehicle for the introduction of a great variety of crops and therefore segregation would be required. Is that a likely pattern that you foresee?

A. Yes, I do. But we view that as a more acceptable development because the whole basis for segregation is different. The products would not be segregated simply because they were genetically modified versus conventional; they would be segregated because the end product had some different characteristic that was preferred by the marketplace. We prefer to see this develop in response to market and consumer demand rather than because of any arbitrary decision by government that these products should be segregated because they are genetically modified.

Lord Wade of Chorlton

400. The point is that that situation might well be reached in Europe. Certain consumers want that choice and if it means extra so be it. You say that these products can be segregated if there is a clear consumer decision to pay the extra cost involved. You and US farmers because of your confidence in the system see no difference in these products. They do not demonstrate any difference. That is not so in Europe. Our people think that they are different. In those circumstances, do you see that segregation can take place on the basis that

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[Continued]

[Lord Wade of Chorlton *Contd*]

they are different products and perhaps command a different price in the marketplace because of segregation?

A. It could develop that way. If it did develop that way it would be a natural development that we would support and endorse. I would view that situation as similar to the current differences between organic and conventionally produced commodities. In general, the public is willing to pay a premium for organic products because it feels that such product are better for whatever reason. But that is a natural development in the marketplace as a result of consumer preferences.

401. You are saying that the initiative to bring about segregation must come from a clear indication by consumers that they are willing to pay for it. Some importing organisation in Europe must then negotiate with specific growers and say, "Okay, you segregate these products and we will deal with it right the way through the chain to the consumer"?

A. Correct.

Lord Moran

402. Would it be practicable at reasonable cost for a supermarket chain in Europe to contract with a group of US farmers to be supplied with unmodified soya given what you say about the fact that US farmers put the product together and it all goes to the same elevator?

A. It depends on one's definition of "reasonable cost". I do not think that farmers would be willing to do it as a matter of routine. They would rather produce and market their commodities mixed together because they would view the soybean as a fungible commodity. Unless it had a different end-use characteristic they would tend to mix the genetically modified with the conventional. But where someone was willing to provide a premium—it would depend on how great it was—our farmers would be willing to undertake the necessary expense of responding to that specific demand.

Lord Rathcavan

403. The Sub-Committee has received evidence that some Brazilian soya producers are supplying non-GM soya products to certain outlets in this country and not at a premium price, so it can be done. Is it correct that the US Government has put pressure on Brazil not to segregate their soya products?

A. It is not correct that we have put any pressure on the Brazilian Government to segregate their products. We have not intervened in that issue in any way at all, as far as I know. To my understanding Brazil has offered soybeans that are not genetically modified, but that is simply because that country has not approved the commercial production of the genetically modified product. Therefore, all it has had to offer is the conventional product. There was no segregation required by any producer in Brazil. In that respect it was very easy for Brazil to say that it could offer only the conventional product. One issue that Brazil faces is whether it should authorise the planting

of genetically modified soybeans for commercial use. From my observation, they will be making that decision over the next year or two, or possibly three. Argentina is another example. Argentina has already approved the commercial production of genetically modified products, so that country is embracing the new technology. Our assumption is that the new technology will continue to spread as long as the approving countries are confident that these products are safe for the consumer and environment.

Lord Moran

404. As I understand it, the US has not ratified the Convention on Biological Diversity but you are taking a role in the negotiations in Montreal now going on in relation to the protocol on the trans-boundary movement of living modified organisms (LMOs). How is that proceeding? What do you understand by the term "LMO"? Do you think that the regulatory structures should apply only to such organisms and not to the products derived from them?

A. You have accurately described the situation in terms of the US's involvement. Even though the US is not a member it is trying to stay engaged in the debate. We hope that the focus in the discussion is on those items that pose significant risks to biodiversity. Our concern, given the current debate, is that notification requirements may go beyond just those products that pose a risk to biodiversity. If such a broad procedure is put in place it may be very harmful and disruptive to trade. The focus of our efforts is to make sure that any agreed procedure would be imposed only in the case of products that posed a significant risk to biodiversity. One of our concerns about the definition of "living modified organism" is that it should not be applied to processed products. We believe that processed products do not constitute a living modified organism.

405. Are you reasonably optimistic that the negotiations will end in a situation that you regard as reasonable?

A. We are not optimistic given where the debate is currently. We are hopeful, not optimistic.

Chairman

406. I am not sure I understand why the United States has not signed the convention. What is the reason for that?

A. I have not been involved in all the various reasons why we have not signed the protocol. I would be happy to provide that for the record, if I may.

407. Is it not a matter of considerable importance, even urgency, that there should be international agreement on many issues raised by genetically modified crops?

A. Legitimate issues have been raised, but the question is: How far do we go with regulation? We say that where there is risk to the importing country, then by all means notification should be required. But if there is no significant risk we do not believe that notification is warranted.

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[Continued]

Lord Wade of Chorlton

408. That would be your decision, not that of the buyer or consumer, on the degree of risk?

A. In this case I do not think that it is just a matter of US determination of the risk. That sort of risk assessment would take place under codex and similar international standards.

Chairman

409. Turning to the subject of trade disputes, is one imminent in relation to GMO? Are you playing a leading role in the pursuit of any trade disputes with the European Union in particular as far as genetically modified crops are concerned? You provided some details about the import of corn into France. There was another case in which imports of corn into Spain and Portugal were in jeopardy.

A. That is an issue that we are following very closely and are concerned about. France's failure to grant final approval on these two corn varieties has meant that we have not been able to ship any corn to Portugal or Spain this year. Because of that we estimate that we have lost about \$200 million in corn sales to Europe in the first six months of this year. In our view this issue must be resolved in about the next two weeks if we are to have an opportunity to ship corn prior to Spain's grain harvest; otherwise, we shall lose all sales opportunity for the year. We will not have an opportunity to recover it.

410. You have not yet received any indication as to whether or not you will be able to move it in the next fortnight?

A. We have not received a final determination.

411. If not, will you be pursuing compensation claims and, if so, against whom would those claims be made? Who would be conducting them?

A. I cannot say here today that we are threatening to pursue a trade dispute. All I can say is that we view the matter very seriously. We are very concerned by the potential loss of \$200 million in trade, but are hopeful that it will be resolved over the next few days.

Lord Moran

412. I want to ask about the general question of consumer confidence. You will know that we have had a hugely damaging and costly problem with BSE in this country and to a lesser extent a problem with *E coli* 0157. As a result, there has been a great diminution in consumer confidence in food products and a reluctance to accept official assurances. This applies not only in this country but throughout the EC. Do you have a view as to how that should be communicated to the consumer? Have consumers in the US been persuaded that GM technology benefits them and not just benefits producers and big companies? Do you think that acceptability would be affected by nutraceuticals and plants containing animal (including human) genes?

A. A number of things come to mind. We are aware that the BSE crisis has probably done a great deal to undermine the confidence of European

consumers in the ability of government to protect consumer health. We are very sympathetic to your predicament in that respect. In the US we are fortunate that consumers tend to have a great deal of faith in the Food and Drug Administration, Environmental Protection Agency and the Department of Agriculture. Perhaps that is why our consumers do not express any apparent concern about biotechnology. It is interesting and ironic that if you asked our consumers what example of agricultural biotechnology they were most aware of it would probably be Dolly the sheep. It is ironic that Dolly was produced here where the concern about agricultural biotechnology is greater. I am not sure why it is that Dolly has received so much attention in the US. Perhaps because she is so cute and it makes for a good photograph. But that is an issue of which everyone is aware. In the US there is acceptance of that technology but it is viewed as more dramatic than genetic modification of plant species. Even though the technology is different, it is all agricultural biotechnology. I think that the average consumer would view cloning as a much bigger and more dramatic step than altering the specific genes of plants.

413. Particularly if it involves human genes?

A. Certainly, the concern in that regard is greater. But I question just how different the concern over genetic modification is here in Europe. As you may know, three or four weeks ago there was a referendum in Switzerland. Up until that time it was assumed that the Swiss public was opposed to that sort of technology. That referendum, which was anti-genetic modification, was defeated two to one. Clearly, in that case the public examined the issue and endorsed the technology. Perhaps there are real opportunities with further education and greater transparency in the whole process to increase public confidence and acceptance of the technology.

414. Concerns have been expressed here by quite serious people. For example, today, English Nature, which is the Government's own adviser on nature conservation, has called for a moratorium on the commercial planting of genetically modified crops until 2002 to allow research to take place. That reflects a degree of public anxiety.

A. I understand. Related to that, certainly the statement of Prince Charles three or four weeks ago also received a lot of attention in the US.

Chairman

415. There are various environmental concerns apart from those mentioned by Lord Moran. Witnesses have referred to concerns about the creation of a super weed and the possibility of the escape of genes from genetically modified plants into their relatives in the wild. In that context, one witness drew attention to the fact that in the United States genetic modification would take place in native species and it posed a huge risk for the US. He did not understand why United States' consumers were not more concerned about it.

A. That is a legitimate issue to raise and examine, just like the issue of resistance, but in the end the question is: What steps are the regulatory agencies taking to guard against any adverse effect? I have to

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MR TIMOTHY GALVIN

[Continued]

[Chairman Contd]

fall back on our confidence that the regulatory agencies are examining those very issues and concluding before they approve any product that the risks are minimal or non-existent. The issue of introducing non-native species is a very broad and important one. It goes beyond the whole question of genetic modification or traditional plant breeding. I recall seeing an article in the papers just a week ago about how a non-native species of fish—the northern pike - had been introduced into a lake in California and it killed all the native trout. The whole issue and risk posed by the introduction of non-native species is something that we face regardless of whether or not the non-native species is the result of genetic modification.

416. If I understood the witness correctly, he was more concerned with the modification of native species of crops in the United States and the greater likelihood that genes could cross with weeds and so on and produce problems in that area.

A. That may be a legitimate concern, but I hope it is one that is fully taken into account by our regulatory agencies before they approve a product.

417. In any event, it is not an issue that has been widely raised by environmental groups or consumers generally?

A. It is raised but, like the issue of resistance, it is one of the matters that is methodically examined as products are submitted for approval.

Lord Moran

418. One of our witnesses, Professor Beringer, who is an expert in this field, raised the question whether there is a hole in our regulatory system in that no Government advisory committee here is looking specifically at the impact of changing agricultural practice on wildlife populations. Is that a concern in the US? Which US regulatory organisation is responsible for that? Is it a real problem?

A. We have not found that to be a particular problem in the US with respect to genetically modified commodities. There is great interest in maintaining or increasing wildlife numbers. We have been quite successful in the US in increasing our bird and deer population—to the point where deer are much more of a nuisance in the US. If we look at black bears, bald eagles and other species, wild life numbers have increased dramatically over the past 20 years because we have a conservation reserve programme that has converted millions of marginal acres of farmland into conservation uses, permanent grassland and so on. All of that has helped wild life numbers to recover. There is an opportunity here with genetic modification because that could increase the diversity of crops. It provides an opportunity to support increased numbers of species. I have an article here which talks about the interest on the part of farmers to “break from the shackles of producing no.2 yellow corn”. No.2 yellow corn is such a standard commodity that today farmers

who want to maximise their income are very interested in trying new and different commodities. That is why they feel that genetic modification is exciting. It may offer opportunities to diversify their production. That is part of the reason they are embracing the technology.

Lord Redesdale

419. One of the problems with the technology is that if something goes wrong and, for example, a superweed is created, it may be unstoppable. Would that be the responsibility of the Department of Agriculture in the US? Who would foot the bill? Would the cost be met by the insurance companies of genetically modified crop producers?

A. I am not sure that if a problem developed it would necessarily be unstoppable. One might be able to control some of the problems that occurred. Generally, it is up to our Animal and Plant Health Inspection Service to try to go out and eradicate any particular weed species that may develop and cause problems. Typically, that agency co-operates with state governments on those kinds of eradication programmes. It may be that someone would have a basis for bringing suit against the manufacturers of a genetically modified product, but it is hard to say if that person would prevail in such a case.

420. If the product became a problem why would it be difficult to sue the manufacturer?

A. It would not be difficult to sue, but I do not know how a court would rule in such a case. I cannot prejudge the outcome of a lawsuit.

Lord Rathcavan

421. Just now you referred to various ways in which you assess risk. As I understand it, the US Government decided that there should not be special legislation to assess the safety of the products of biotechnology. How adequate or useful do you consider your pre-commercialisation risk assessment to be? What can usefully be judged in the four and a half months which the US took to assess Monsanto's pest-resistant corn or the eight months to assess the herbicide-resistant soybeans? You are probably aware that there has been great concern in Europe about the resistance to antibiotics which is potentially involved in one particular pest-resistant corn, although many believe that the risk is minimal. Perhaps it would be useful to hear how the US system assesses this risk for that BT maize or pest-resistant corn. Undoubtedly, there was great public concern that in some way immunity to antibiotics could enter the food chain?

A. The role of pre-commercialisation testing and research is very important. Typically, before the sponsors of these products approach the US Government and ask for commercial approval they conduct at least a couple of years' worth of field testing. That field testing is done under standards prescribed by the federal agencies that will ultimately review the product. You mentioned the number of months that a product is before the different regulatory

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[Continued]

[Lord Rathcavan *Contd*]

agencies. As I understand it, that simply refers to the period of time during which that final stage of the process occurs where the company has completed its couple of years' field testing and is now providing the data to USDA or EPA to get approval to move on to the commercial phase of production. It is not as if those products are examined for only four or six months. That is just the final stage of the process prior to full-fledged commercialisation. In the case of antibiotic markers, a lot of attention has been focused on that issue. That issue was examined by the French during their consensus conference three or four weeks ago. It has also received careful scrutiny in the US. It looks as if most of the scientists who have examined the issue are confident that the procedures are safe. But I believe that the companies are aware of the sensitivities in this matter and for that reason seem to be interested in other alternatives as new products are submitted in the future.

Lord Redesdale

422. You said that the final stage of field testing was undertaken by the individual companies. Are those field trials attended by independent scientists who verify the results or is it done specifically by the company and you take the results submitted by the company?

A. I cannot tell you about the exact procedures. All I can say is that the test protocols are laid down by our federal agencies at the start. The companies have to follow those protocols. Whether or not the federal agencies send out people to make sure that those protocols are followed I am not able to say today.

Chairman

423. Does the USDA or any other agency require any follow-up monitoring after commercial release of particular crops?

A. We generally require monitoring, unless a product has been deregulated. Companies are required to notify the federal government of any adverse findings that may be discovered. To cite a specific example, our EPA has required monitoring for Bt-based crops, primarily to monitor for insect resistance.

424. Does that requirement rest on the company that provides the seed to the farmer?

A. The company or anybody who may experience adverse findings. The company is obligated to report that to the government.

425. Is that a statutory requirement? If any ill-effect was subsequently discovered and not reported, the person who should have notified it but did not would be pursued and prosecuted?

A. It is more a regulatory than statutory requirement.

426. The farmers and companies are told what they should be monitoring?

A. That is my understanding. I believe that that information is explained in the detailed answers to the other questions that I have submitted.

427. Perhaps I can link the question of risk assessment to one matter we discussed earlier; namely, the possibility of an international convention. Is there not a need for some internationally agreed worldwide standard for risk assessment; otherwise, who will decide on the validity of the assessment? Does every importing country have to accept the risk assessment of every exporting country, or how should it be regulated?

A. I do not know that there needs to be an international standard for everything, but I believe that the burden on either the exporting country or the importing country that challenges the product is to demonstrate whether or not sound science has been used. I think of the other current issue between the US and EU over hormones used in beef production. The US believes that the science is very clear. We have provided all the information to the WTO, for example. The burden is on those who would challenge that decision to prove that somehow the science is flawed. After examination it has been proved that with respect to hormones in beef science is on our side. The burden tends to shift depending on who is raising the challenge.

Lord Gallacher

428. What crops or animals are now being worked on as regards genetic modification? Will the present focus of benefit to farmers continue? Are modifications at present benefiting US consumers, and will that also continue?

A. If I may, I would like to provide the Sub-Committee this morning with a list of all the various products that have been approved and are available to the marketplace today, as well as a list of products that are likely to be available over the next six years. This list is publicly available on the web page of an organisation called the Biotechnology Industry Organization. Basically, it is made up of all the companies that are active in this area. If one goes through the list one sees that 40 or more products are currently available to the marketplace today. Some of those offer direct benefits to consumers. Looking at the products, they include: tomatoes; carrots; sweep peppers; cherry tomatoes; and high-oil soybeans. There is an enzyme that is used in approximately 60 per cent of all hard cheeses. In the case of tomatoes, there is longer shelf life or improved taste. They offer direct benefits to the consumer. But I argue that even in the case of some of the other commodities like corn and soybeans, where it appears that the benefits accrue only to the producers, the public as a whole benefits to the extent that use of these products has resulted in reduced pesticide and herbicide use. We all benefit from that improved environmental stewardship. One does not necessarily have to taste a sweeter tomato or something of that kind in order to realise some of the benefits of this technology. Looking to the future, some of the other products that the industry say will be available six years from now include improved cotton varieties with stronger fibres that reduce pollution from dyes; a number of high-oil products, whether it be corn or soybeans; sweeter tomatoes and

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[Lord Gallacher *Contd*]

strawberries; seedless melons; controlled ripening in bananas and pineapples; firmer peppers; sweeter peppers and peas. The list goes on and on. I would be happy to provide that list to the Sub-Committee. (See *Appendix to Supplementary Memorandum*).

Lord Moran

429. Does that include work on animals? So far you have spoken only about plants.

A. The only mention I see here of animals are some fish: salmon, trout and flounder. Basically, they grow faster as farm-raised fish.

Lord Willoughby de Broke

430. What is the increased growth rate?

A. It is only a paragraph which refers to fish being capable of growing to market size in one to one and a half years as opposed to conventional techniques that require three years.

Lord Rathcavan

431. The last question was aimed at discovering who benefited more—the consumer or farmer. Quite a lot of our evidence reveals that the view of people is that it is Monsanto who benefits most rather than the consumer or farmer. There is quite a strong feeling about the monopolistic role of Monsanto in the development of GM technology. We heard about Monsanto dominating the cotton business in China and buying up companies in this business. Does Monsanto's monopolistic position in GM crop technology concern you?

A. It is interesting and ironic that Monsanto is frequently put up as a kind of straw man on this issue. From my experience, we deal with a number of companies including European companies. Representatives of Novartis and Agrevo come to see us on a regular basis with respect to GMO commodities for which they seek approval in the US. Certainly, European companies are very active in this area, as they should be. It is a bit of a puzzle to me why Monsanto is always held up as an example. That said, I agree with your observation that there is concern about the level of consolidation that is occurring in this industry. We see various companies either buy out each other horizontally in the development of these products or move to the next stage and buy out and consolidate the various seed companies. There is concern about increased market concentration. But today even with these acquisitions there is still a fair degree of competition, in part because European and other companies are very active in this area. Farmers are right to be concerned about the direction in which things are moving and whether or not a sufficient level of competition will be present in the industry in 2010, 2020 and that sort of timeframe.

432. We heard from the American Soybean Association about farmers' reduced freedom when

growing modified soybean crops and the amount of litigation that is threatened if they do not conform to the standards set by Monsanto in this area. Is your department aware of the reduction in the freedom of farmers to produce crops as they want?

A. We are certainly not there yet. Today, farmers still have plenty of choices in the marketplace. Genetic modification technology offers the potential dramatically to increase choice, so long as there are a number of companies engaged in developing these products and offering them to farmers. There is nothing inherent about genetic modification that is spurring the concentration that we see occurring. If you look at the history of hybrid corn development over the past 50 years, a concentration has occurred in that industry. One can make the case that maybe hybrid corn is bad too. I do not think that anyone is ready to reach that conclusion. There is nothing inherent in this genetic technology that indicates that there is a problem, but farmers have a legitimate concern about the current rate of acquisitions and concentrations that occur. But at least in the US farmers for the past 100 years have always been concerned about monopolies and concentrations within agriculture, whether it is in railroads, meat-packing or grain companies. They are always worried about maintaining a level of competition with respect to where they buy their inputs or sell their final product.

Lord Willoughby de Broke

433. I want to pursue the question of herbicides and pesticides. With non-GM crops farmers have traditionally had a wide range of companies from whom they buy their supplies. As I understand it, nearly all the GM companies link their products with their own herbicides. People are told that they must use their herbicide with their seed; that's what the product's designed for. I was not at the meeting with the American Soybean Association, but I imagine that that is the sort of concern that it raises. Is that a matter of concern to you?

A. I do not perceive it as "must use". However, as a practical matter if one is buying round-up ready soybeans one is buying that product so one can use the round-up herbicide in conjunction with it. It is not a question of "must use"; if one is buying that particular seed one is buying it so one can use it in conjunction with round-up ready. As the patent on round-up expires in a couple of years I assume that it will be a generic herbicide. Others can produce it and farmers can buy it from other companies.

Chairman

434. That brings us to the end of our questions. You have answered them very fully and clearly. We are extremely grateful to you for having come to see us.

A. Thank you for the opportunity. I view it as a special honour to be here today.

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Supplementary Memorandum from United States Department of Agriculture**US REGULATION: PROCESS**

11. Would you explain the procedure the USDA uses to (a) approve field trials and (b) permit commercialization of a new genetically-modified crop?

What is the legal status of an "deregulated" or exempted crop? Do you still monitor such crops in any way? Are these "traceable"? If the exempted crop were to prove to be a problem, is there any way of withdrawing the exemption?

Answer:

A. Approve field trials

The Animal and Plant Health Inspection Service (APHIS) of the USDA, as part of its overall responsibilities to protect American agriculture against pests and diseases, exercises oversight for the importation, interstate movement, and the field testing of most genetically engineered organisms, particularly most new plant varieties, and assures that these new varieties are as safe to use in agriculture as traditional varieties (the term "genetically engineered" means those organisms derived through the use of recombinant DNA techniques).

The development process for a new test organism typically involves steps in which the new organism (which we call a "regulated article") leaves the lab in which it's developed and is imported or moves interstate or is planted in the open environment. Those actions require permission from APHIS, in essence a certification that the action will be performed in a safe manner. As testing proceeds, an applicant gathers information typically to establish for him/herself that the product has the new intended property, and also gathers information to demonstrate that the organism is safe to grow in the environment. When enough information is gathered, the applicant petitions APHIS for a Determination of Nonregulated Status.

USDA procedures provide different options for the conduct of field trials. Our regulatory approach incorporates the use of performance standards which focus on results, *rather than design standards*. For example, APHIS has two options under which applicants can seek regulatory approval to conduct field trials. One is our notification procedure, under which there are clear eligibility criteria for its use and performance standards for assurance of safety. The other is our original, traditional permitting procedure which continues to be required for some field trials that are not covered under notification, such as those involving genes encoding products intended for pharmaceutical use.

The streamlined notification alternative does not compromise safety. Field tests under either option must be performed at comparable levels of confinement and care, standards that we have spelled out clearly. These standards have been demonstrated to be both sufficient to ensure that field tests are safely conducted and also achievable in practice. The standards have been met in each of the field trials involving transgenic plants that have been conducted in the US and its territories.

Under notification, it is the applicant's responsibility to certify that he or she will adhere to a set of performance standards. USDA officials, as well as our State counterparts, have the option to inspect test sites at any time to verify that those standards are being met and maintained. We never lose the option of requiring additional information from an applicant about the conduct of the trial if we have some concern that in the particular instance a performance standard may be difficult to meet.

B. Permit (allow) commercialization of new engineered crop

As a point of clarification, we use the term "permit" for field testing and "*petition*" for the process of deregulation of an engineered plant.

As field testing proceeds, an applicant gathers information typically to establish for him/herself that the product has the new intended property, and also gathers information to demonstrate that the organism is safe to grow in the environment. When enough information is gathered, the applicant petitions APHIS for a Determination of Nonregulated Status. APHIS announces receipt of the petition, solicits public comment, and reviews the submitted petition information as well as other scientific information our scientists obtain.

If we agree, we issue the determination, along with a Finding of No Significant Impact under the main environmental statute in the United States, called the National Environmental Policy Act (NEPA). All Federal regulatory agencies have to comply with NEPA for any regulatory action that they take. Once such a Determination of Nonregulated Status is issued, the new variety or plant line may be treated, from USDA's perspective, like any other variety of the crop: i.e., it may be grown, tested, or enter traditional crop breeding programs without any other special oversight on the part of APHIS. Once any other requirements from other agencies (such as the FDA or EPA) are satisfied, it can enter into commerce and be sold or, if it's a commodity like corn, perhaps mixed in silos with other varieties.

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In the US, therefore, new products destined for commodity streams are grown by farmers, shipped to silos or grain elevators, and shipped either directly to processors, or to container ships and then to processors, with each of those steps again usually based on independent contracts between two independent entities. These steps are only regulated by the standard procedures that govern the shipment of the unmodified commodity.

C. *What is the legal standing of a deregulated crop?*

Once such a Determination of Nonregulated Status is issued, the new variety may be treated, from USDA's perspective, like any other variety of the crop: it may be grown, tested, or enter traditional crop breeding programs without any other special oversight on our part. A new variety is not used as food or feed unless the applicant has completed the consultation with FDA. If the plant is pest resistant or herbicide tolerant, EPA approval of the plant, or changes to the list of allowed uses for the particular herbicide, may also be required.

D. *Do you monitor such crops?*

To date, no post commercialization monitoring has been found to be necessary and therefore has not been required by USDA.

E. *Are these traceable?*

The USDA does not require that applicants provide us any unique molecular tag that would allow identification of a specific engineered seed in a mixture of engineered and nonengineered seeds.

F. *If there is a problem with a crop, is there a way of withdrawing the exemption?*

Yes, USDA has the authority to regulate any plant that poses a plant pest risk.

NEW QUESTION

12. Why did the US decide to use existing laws to regulate the products of biotechnology? Why did the US develop new regulations under these laws?

Answer:

The United States believes that the use of existing health and safety laws provided more immediate regulatory protection and certainty than was possible with new legislation specific to biotechnology. Moreover, there did not appear to be an alternative, unitary statutory approach because the broad spectrum of products obtained through genetic engineering cuts across many different types of products regulated by different agencies. The United States believes that the new techniques of genetic engineering are an extension of biotechnology in general and, thus, new products developed through these techniques are extensions of existing product classes.

EXEMPTIONS

13. Could there be any GM plants which would not require surveillance of any kind from the USDA; for example, a flower modified by using a gene gun?

Answer:

In the sense of "surveillance" as regulatory oversight:

A regulated article is an organism that has been genetically engineered (using recombinant DNA techniques) from a donor organism, recipient organism, vector or vector agent that is a plant pest or contains plant pest components. Other genetically engineered organisms may be regulated articles if they have been genetically engineered using unclassified organisms or if APHIS determines that the genetically engineered organism is a regulated article.

Thus, somaclonal variants and protoplast fusion techniques do not meet our definition of "genetically engineered." Some generically engineered plants do not contain any plant pest components. For field testing, however, companies do submit voluntarily for APHIS' approval for field testing of all engineered plants, irrespective of whether they contain plant pest components. To date, all commercialized engineered plants have met the definition of regulated article and have been reviewed by APHIS.

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RESPONSIBILITIES

14. Can you explain the different responsibilities of the USDA, the EPA and the FDA when considering the use of GM products? Does an applicant apply to each agency, or is there a central "clearing house" for the product—i.e., does deregulation by the USDA imply clearance for food, feed or drug use?

Answer:

The Agencies primarily responsible for regulating biotechnology in the United States are the US Department of Agriculture (USDA), Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Products are regulated according to their intended use, with some products being regulated under more than one agency.

Before commercialization, genetically engineered plants/organisms must conform with standards set by State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), and the Federal Plant Pest Act. There are no national requirements for varietal registration of new crops.

Each US agency regulates GM products under separate statutory authority. Therefore, firms apply separately to the relevant agency depending on the nature or characteristics of the product.

Here are some examples of common types engineered plants and which Agency has regulatory responsibility. This information is available at United States Unified Home page for biotechnology at <http://www.aphis.usda.gov/biotech/OECD/usregs.htm>.

New trait/organism	Regulatory review conducted by	Reviewed for
Viral resistance in food crop	USDA EPA FDA	Safe to grow Safe for the environment Safe to eat
Herbicide tolerance in food crop	USDA EPA FDA	Safe to grow New use of companion herbicide Safe to eat
Herbicide tolerance in ornamental crop	USDA EPA	Safe to grow New use of companion herbicide
Modified Oil content in food crop	USDA FDA	Safe to grow Safe to eat
Modified flower color ornamental crop	USDA	Safe to grow

A. APHIS responsibilities

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting US agriculture from pests and diseases. Under the authority of the Federal Plant Pest Act, APHIS regulations provide procedures for obtaining a permit or for providing notification, prior to "introducing" a regulated article in the United States. Regulated articles are considered to be organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. The act of introducing includes any movement into (import) or through (interstate) the United States, or release into the environment outside an area of physical confinement. The regulations also provide for a petition process for the determination of nonregulated status. Once a determination of nonregulated status has been made, the product (and its offspring) no longer requires APHIS review for movement or release in the United States.

B. EPA responsibilities

In the area of agricultural biotechnology, EPA currently regulates the following types of products: "plant-pesticides", EPA's term for substances in plants (and the genetic material necessary to produce them) that humans intend to use to prevent, destroy, repel or mitigate a pest; used for example to protect crop plants in the field or for post-harvest protection; plant-pesticides in food; microorganisms used as pesticides; microorganisms used for enhanced nitrogen fixation.

Plant-pesticides: The term "plant-pesticides" is the designation EPA gives the substances (and the genetic material necessary to produce them), that plants produce for protection against pests. In 1994, EPA made the

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interpretation that these substances, produced and used in living plants, are pesticides if humans intend to use them for "preventing, destroying, repelling or mitigating any pest".

EPA regulates use of pesticides, including plant-pesticides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through a registration process. No person may distribute or sell in the United States any pesticide that is not registered or exempted from the requirement of registration. Before a pesticide can be registered, it must be shown that when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects to human health or the environment.

Since 1994, EPA has registered eight plant-pesticides. To date, the plant-pesticides registered by EPA have been insecticidal proteins, of bacterial origin, which are regulated under FIFRA when they are formulated in products to be sprayed/dusted on plants. Under FIFRA, EPA performs an assessment of both risks and benefits associated with use of the pesticide using data submitted to EPA by registrants, and on other available information from scientific literature. Under its approach, EPA registers the plant-pesticide for use in a crop. It does not regulate the plant, *per se*. For example, EPA has registered a delta-endotoxin from the bacterium *Bacillus thuringiensis* for use in cotton against certain lepidopteran pests (certain caterpillars and moths).

EPA is also responsible for regulating plant-pesticides in food under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Before food containing a plant-pesticide can be marketed, FIFRA and FFDCA require that EPA establish a tolerance (i.e., a limit on the amount of pesticide residue that may be in food) or establish an exemption for the plant-pesticide from the requirement of tolerance. Food includes articles used for food or drink by humans or other animals. A food containing a plant-pesticide may not be moved in interstate commerce without an appropriate tolerance or an exemption from the requirement of a tolerance.

EPA is currently using regulations originally drafted for chemical pesticides to regulate plant-pesticides. EPA wishes to issue regulations specifically tailored to plant-pesticides. In 1994, EPA proposed several regulations to begin this tailoring for plant-pesticides. EPA intends to issue these regulations in final form in 1998.

FIFRA gives EPA the authority to issue "Experimental Use Permits" (EUP) to allow field testing in order to gather the data necessary for registration. Under current regulations, potential registrants apply for a permit when the testing occurs on 10 acres or more of land (or one surface acre of water). EPA has issued a number of EUPs for field testing of plant-pesticides.

Microorganisms used as pesticides: FIFRA gives EPA the authority to regulate all pesticides, no matter how they were made or their mode of action. The first registration of a microorganism used as a pesticide occurred in the United States in 1948. To date, hundreds of pesticide formulations, based on some 20 different microorganisms, have been registered. Regulations appropriate to the characteristics of microbial pesticides are in place under both FIFRA and FFDCA section 408.

The FFDCA section 408 requirements apply to microbial pesticides in food. Regulations for field testing of microbial pesticides are in place.

Micro organisms used for enhanced nitrogen fixation: EPA regulates this type of product under the Toxic Substances Control Act (TSCA) when the micro organism is "new" within the meaning of TSCA. "New" micro organisms are those formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera. TSCA excludes from its jurisdiction products covered by FFDCA and FIFRA. Thus, it does not cover pesticides, foods, drugs or cosmetics. In the area of agricultural technology, the only product EPA has reviewed to date are micro organisms used for enhanced nitrogen fixation. EPA has, however, reviewed micro organisms used for other types of applications, e.g., bioremediation and production of speciality chemicals.

TSCA gives EPA broad authority to gather information on and evaluate the risks of chemical substances and mixtures of chemical substances. It also gives the Agency the authority to regulate identified risks. EPA has made the interpretation that living organisms are mixtures of chemical substances and thus subject to TSCA.

EPA's regulations for micro organisms under TSCA address both field testing and commercial use.

C. FDA responsibilities

The FDA is responsible for food safety and labelling for all foods, food ingredients, and additives (domestic and imported), except for meat and poultry products which are regulated by the USDA. Thus, the FDA's responsibility includes all fruits, vegetables, cereals, and by-products such as vegetable oils and food starch; milk; fin fish and shell fish; and flavours, preservatives, sweeteners, and other additives used in food. The FDA also regulates drugs used in animals, including food producing animals (e.g., rBST used to increase milk production) and human drugs and biologicals produced from plants and animals.

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D. Does deregulation by the USDA imply clearance for food, feed or drug use?

FFDCA does not give EPA the authority to delegate its responsibilities for plant-pesticides in food or feed to USDA. EPA has not delegated its responsibility under FIFRA for plant-pesticides or micro organisms to USDA. In the case of FDA, deregulation by APHIS does not imply clearance as food, feed, or drug.

WIDER ISSUES

16. Does the US only assess products for safety, or would other issues be considered? Could a permit be refused, or growing conditions imposed, if an adverse impact on the environment were thought possible? By whom?

Would the US take into account the presence of alternative equivalent products already on the market? Does your risk assessment consider the risk to the non-agricultural environment and could a permit be refused if an adverse impact on the environment were thought possible? If this is not the responsibility of USDA—APHIS, whose responsibility is it?

Answer:

A. APHIS

APHIS' analyses are based on the principle that: *the environmental risk that may be posed by a certain use of a particular organism will depend on: the properties of the organism, the way the organism is to be used (including whether the organism is to be used under containment or in the context of an environmental release), and safeguards that are built into experimental design or conditions of use.*

We have worked closely with member countries of the Organisation for Economic Co-operation and Development, the OECD, and in other fora, to bring about international consensus on the safe development, testing, and use of genetically modified plants and microorganisms.

In performing risk assessments, we have recognised that it is necessary to identify, and focus on, specific issues that are potential components of risk based on the particular organisms in question or the particular use; for example, plants intended for use in agriculture, or to be eaten as food, or used to make ingredients in food. To identify these risk components, it is necessary to start with a good understanding of the existing traditional knowledge base and of the procedures that are routinely carried out in the course of developing any new crop variety that is released for commercial use. This knowledge serves as a baseline to decide whether any identified risk is significantly changed in potential magnitude from any well-known one that is part of established practice.

How are environmental risk assessments performed? *Broadly speaking, we follow Annex 3 of the UNEP Guidelines for Safety in Biotechnology*, which lays out the broad steps in biosafety review. These can be paraphrased as:

- (1) *identifying hazards;*
- (2) *assessing actual risks that may arise from the identified hazard;*
- (3) *determining how identified risks can be managed and whether to proceed with proposed action;*
- (4) *comparing the assessed risks with those posed by actions with comparable organisms.*

In our risk assessment processes, we focus on the key concept of familiarity. In 1989 National Research Council, an arm of the US National Academy of Sciences, published its report entitled, "Field Testing Genetically Modified Organisms." One conclusion reached was that the use of plants modified by classical breeding techniques for field testing has a history of safe use. That crops modified by engineering should pose risks no different from those modified by classical genetic methods or *similar traits*. Thus, if the genetically modified plant is phenotypically similar to a plant that has been (or could be) bred by traditional breeding techniques this parallel association is called familiarity. The concept of familiarity allows regulators to draw on past experience with introduction of modified plants into the environment. Familiar does not necessarily mean safe. It does mean that the level of risks associated with the introduction of new pest resistance genes into plants by classical methods and the evaluation of new cultivars by national variety registration agencies, has made the introduction into the environment of these types of modified plants of negligible risk. Other important familiarity factors are whether the plant is new to the particular environment where it is intended to grow, the nature of the trait (gene), and that the evaluations should be made on a case-by-case basis. All engineered crop plants that have been commercialised in the United States to date have been grown in the same environment that their nonmodified progenitors were grown in. The OECD has also recognised the concept of familiarity as a basis for evaluation of genetically modified crops.

What are the sorts of issues that we concern ourselves with, with respect to genetically engineered plant species? The types of safety issues that are raised by these plants are no different in kind from those with which

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we are already familiar from traditional breeding, though the magnitude of any particular risk may differ. Apart from the case where the introduction of a wholly new species into a specific environment is under consideration, the environmental issues with respect to plants center around their potential for survival, and even more particularly, the potential for enhanced weediness.

Specifically, do the introduced traits specifically affect the ability of the plant to survive stresses, or to disseminate pollen or other propagules, or to confer increased survival on those propagules, or to resist particular pests known to play a major role in limiting the plant's survival outside of cultivation? Gene movement, however, is not in and of itself a risk. Genes move freely around via pollen, and interbreeding between compatible species is a matter of statistics, wind currents, and pollinators. USDA's focus is on the specific trait, potential recipients of that trait, and the potential effects.

B. EPA

EPA will refuse to register a pesticide if the Agency determines use of the product could result in an unreasonable adverse effect. EPA also has the authority to make a registration conditional on the use of specified growing conditions. Such conditions would be imposed if the Agency determined that the conditions were needed to ensure that no unreasonable adverse effects occurred. EPA statutes give EPA authority to address all aspects of the environment.

IMPORTS

17. Do the US agencies accept products without further scrutiny that have undergone safety assessment procedures in other countries? For example, would you accept products from (a) Canada; (b) Mexico; or ©China?

NIH Guidelines explicitly indicate that products in confinement would be acceptable if the safety assessments are equivalent to those supposedly done in US laboratories.

Answer:

USDA/APHIS

USDA/APHIS has allowed commodities that have undergone safety assessments in Canada to enter the US for processing (not for planting). Our approval was based on our experience with similar types products and our analysis of the Canadian decision document on these commodities. Since we have had bilateral negotiation with Canada for more than a decade, and Canada has reviewed many of the same products that we have, we have a deep understanding of the similarities in our review processes. Our approval was contingent on completion of the food safety consultation process for the commodity at FDA (the plants were not engineered to produce a substance with pesticide activity).

In addition, APHIS has allowed carnations engineered for altered flower color to be imported as cut flowers. In their customary use, these cut flowers are virtually nonviable. Regulated articles must be viable.

EPA

Under FIFRA, no person may distribute or sell in the United States any pesticide that is not registered or exempted from the requirement of registration. Thus, pest resistant, genetically modified seeds being imported into the United States to be planted would need to comply with the registration requirements under FIFRA. Commodities, not intended to be planted (i.e., used as a pesticide) would not have the same requirements under FIFRA as imported seeds.

Under FFDCA, a food containing pesticide residues may not be moved in interstate commerce without an appropriate tolerance or an exemption from the requirement of a tolerance. Under TSCA, an importer must submit a notice to EPA 90 days before importation commences.

FDA

The FDA believes that it is prudent practice for firms, both domestic and foreign, to consult with the FDA regarding GM products prior to commercial distribution in the US. Products that comply with the Federal Food, Drug, and Cosmetic Act may be imported into the US. The FDA has published guidance for industry and procedures by which firms may consult with the FDA.

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NEIGHBORING COUNTRIES

18. Is there any procedure for consulting neighboring countries prior to approval for commercialisation? For example, would the US consult Mexico before crops are approved where Mexico is the center of origin?

Note for questioner: All the maize in the world originates from Mexico and many Mexican plants and weeds are thus related to it. Pollen could blow across the border from the US or farmers could illegally carry plants across the border into Mexico. The chance of the GM maize crossing with Mexican relatives is thus much higher than anything that might happen in the US and it follows that the super weed problem is potentially much greater than, for example, between the US and Canada. "Genetic pollution" is also an issue.

Answer:

For more than a decade, USDA/APHIS has had yearly bilaterals with Canada and Mexico (individually) on issues related to field testing and commercialization of engineered plants. Other discussions have been held trilaterally as members of NAPPO (North American Plant Protection Organisation). USDA has conducted workshops to share its experiences in reviewing transgenic plants during field testing and commercialization phases.

For those countries with which the US shares ocean borders, USDA has participated in ongoing bilateral discussions on biotechnology and the environment with Directorate General XI of the European Commission. As a member of the US/EU Biotechnology Technical Working Group, USDA has been very active in sponsored workshops on environmental reviews associated with field testing and commercialisation.

USDA has also been an active member in APEC, participating in similar workshops on evaluating environmental safety prior to commercialisation of transgenic plants.

USDA/APHIS provides list of all field tests and plants under review for deregulation at our home page <http://www.aphis.usda.gov/biotech/>. This list is updated daily.

ZONING

19. Can a crop be given permission for commercialization in one part of the USA and not in another due to climactic or other scientific reasons?

What conditions could be applied if this were a federal requirement? Could any individual State refuse to allow cultivation of a GM crop even though permission had been given nationally, or could they impose stricter conditions than those imposed under Federal law.

Answer:

To date, all USDA approved engineered plants can be grown anywhere in the US. The USDA has authority to restrict movement of plants for scientific-based (e.g., phytosanitary) reasons. The deregulation of an engineered plant by APHIS is just the first step in its ultimate commercialization. EPA can geographically restrict the authorization of pesticides within the United States. Besides EPA and FDA oversight, some plants may have to be further tested under the State variety registration laws. All engineered plants must meet the same State imposed regulation for the specific plants. For example, all engineered potatoes must meet pathogen indexing requirements.

EPA has issued a registration for a plant-pesticide (in corn) allowing seed containing the plant-pesticide to be sold to farmers in most of the United States for planting, except for some cotton growing areas in the southern United States. This geographic limitation on sales was placed on the registration to reduce selection pressure on an insect pest that feeds on both corn and cotton. This measure was taken to attempt to manage the tendency of insect pests to become resistant to pesticides, in this case resistance to a delta-endotoxin from the bacterium *Bacillus thuringiensis* (Bt).

AGRICULTURAL BIODIVERSITY

20. If many farmers choose to grow a GM variety to the exclusion of others, there may be a reduction in agricultural biodiversity. Are you (or the EPA) concerned about this, and what can be done to maintain diversity?

Answer:

In the early 1970s, the US National Academy of Sciences addressed the question, "How uniform genetically are the crops upon which the nation depends and how vulnerable are they to epidemics? Their answer was that "most major crops are impressively uniform genetically and impressively vulnerable." For example, 53 per cent of the cotton crop is planted to only three varieties and 71 per cent of the corn to six varieties. APHIS believes that most of the major crops are just as genetically uniform, if not more so, than they were 25 years ago. The

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factors that govern farmer acceptance of new crop varieties are not in any way unique to GM varieties. Rather, the introduction of new genes by engineering could tend to diversify the genetic makeup of major crops in the United States.

APPENDIX

BIOTECHNOLOGY AGRICULTURAL PRODUCTS ON THE MARKET

Liberty Link™ Corn (Produced by AgrEvo®)—Introduced in 1997, Liberty Link™ Corn allows growers to apply Liberty herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield. Liberty Link™ Corn hybrids are offered by seed company partners; Liberty™ herbicide is offered by AgrEvo®.

Liberty Link™ Canola (Produced by AgrEvo®)—Introduced in 1995, Liberty Link™ Canola allows growers to apply Liberty™ herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield.

IMI-CORN® (Produced by American Cyanamid)—Introduced in 1992, imidazolinone-tolerant and—resistant corn allows growers to apply the flexible and environmentally friendly imidazolinone herbicides to corn. Registration of LIGHTNING™ herbicide, a new imidazolinone specifically for use on IMI-CORN®, was approved by the EPA on March 31, 1997. One post-emergence application of LIGHTNING™ herbicide provides both contact and residual control of broadleaf and grassy weeds, resulting in maximum yield potential.

IMI™ Canola Seed (Produced by American Cyanamid)—Introduced in 1995, imidazolinone—tolerant canola allows growers to apply environmentally friendly imidazolinone herbicides to canola. In Canada, registration of ODYSSEY™ herbicide, a new imidazolinone for use on imidazolinone-tolerant canola, was approved on April 4, 1997. One post-emergence application of ODYSSEY™ herbicide provides both contact and residual control of hard-to-control broadleaf and grassy weeds, resulting in maximum yield potential.

Freedom II™ Squash (Produced by Asgrow)—Squash with a natural resistance to plant viruses.

BXN® Cotton (Produced by Calgene, Inc)—BXN® cotton plants that require less chemical herbicides.

FLAVR SAVR™ Tomato (Produced by Calgene, Inc)—The Flavr Savr™ is a high-quality, fresh market tomato that has been modified using antisense technology¹ to ripen on the vine.

Laurical® (Produced by Calgene, Inc)—A less-expensive source of high-quality raw materials for soaps, detergents and cocoa butter replacement fats. Rapeseed plants with more than 35 per cent laurate in oil have been produced.

Novartis Maximizer TM Hybrid Corn (Produced by Novartis)—This corn is modified to have natural protection against the European corn borer, one of the most devastating insect pests in modern US agriculture.

DEKALB™ Insect-Protected Hybrid Corn (Produced by DEKALB Genetics Corporation)—Approved in 1997, select DEKALB leader hybrids are now available with built-in protection against the European corn borer.

DEKALB GR Hybrid Corn (Produced by DEKALB Genetics Corporation)—Approved in 1996, DEKALB GR hybrids provide growers the added weed control benefits of over-the-top glufosinate herbicide application during the growing season.

FreshWorld Farms® Tomato (Produced by DNAP Holding Corporation)—The FreshWorld Farms® tomato is a premium, fresh market tomato developed through *somaclonal variation*² to have superior color, taste and texture and a 10- to 14-day shelf life.

FreshWorld Farms Endless Summer® Tomato (Produced by DNAP Holding Corporation)—The Endless Summer® tomato is a genetically engineered version of the FreshWorld Farms® tomato on the market since April 1993 and shares its superior colour, taste and texture. What's new is a greatly extended shelf life of more than 30 to 40 days after harvest. Company scientists used Transwitch® technology to suppress production of ethylene, the hormone that causes tomatoes and other fruits to ripen. It is the company's first whole-food product developed through recombinant DNA technology.

FreshWorld Farms® Carrot Bites (Produced by DNAP Holding Corporation)—FreshWorld Farms® carrot bites are crisp, juicy baby whole carrots that are peeled and washed, ready-to-eat, in one-pound bags.

¹ Antisense technology involves taking the gene in the tomato that is responsible for softening, creating a duplicate of that genetic sequence in reverse and inserting it in the tomato. The new genetic information effectively turns off the softening process, which allows the tomato to ripen longer on the plant.

² Somaclonal variation is a biotechnology process that involves breaking a plant sample down to its individual cells, putting the cells in a growth medium and regenerating new plant clones from the cells. The new plants will have a broad diversity of characteristics. The new plants with the desired characteristics are then used to create new plant lines through traditional breeding techniques.

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FreshWorld Farms® Sweet Mini-Peppers (Produced by DNAP Holding Corporation)—The FreshWorld Farms® sweet mini-pepper has a novel sweet taste, deep red color and is nearly seedless. It was developed through another culture, an advanced breeding technique that captures and stabilizes preferred characteristics such as taste, texture and low seed count.

FreshWorld Farms® Cherry Tomatoes (Produced by DNAP Holding Corporation)—The FreshWorld Farms® cherry tomato is specially bred for superior taste, color and texture. It is sold through distributors and supermarket chains in the mid-Atlantic, Northwest and Midwest regions.

High Oleic Acid Soybeans (Produced by DuPont Agricultural Products)—These soybeans produce an oil containing higher levels of oleic acid, (82-85 per cent) than found in currently available soybean oil (24 per cent) and also containing lower levels of saturated fat. The oil will fit applications that require stability without the need of chemical hydrogenation.

High pH Tolerant Corn Hybrids (Produced by Garst Seed Company)—These corn hybrids are capable of growing successfully on the severely alkaline soils that characterise the western United States corn belt.

Gray Leaf Spot Resistant Corn Hybrids (Produced by Garst Seed Company)—Corn hybrids tolerant to the disease *Cercospora* ~spp., which attacks corn hybrids in the central and southeastern corn belt.

G-Stac™ Corn Hybrids (Produced by Garst Seed Company)—Corn hybrids featuring “stacked” genes providing multi-task capability. For example, hybrids that contain genes for the control of European corn borer (Bt), genes for resistance to Liberty herbicide and genes for resistance to imidazolone herbicide all in the same corn hybrid.

Chymogen® (Produced by Genencor International and Marketed by Chr. Hansen's)—Chymogen is the biotechnology-produced version of an enzyme (chymosin) found in calves that makes milk curdle to produce cheese. Because it is produced through biotechnology, it is purer, more plentiful and eliminates variability in the quality and availability of calves' stomachs. It is used in approximately 60 per cent of all hard cheese products made today.

Bollgard® Insect-Protected Cotton (Produced by Monsanto)—Introduced in 1996, cotton with Monsanto's Bollgard gene is protected against cotton bollworms, pink bollworms and tobacco budworms.

New Leaf® Insect-Protected Potato (Produced by Monsanto)—Introduced in 1995, the NewLeaf potato is the first commercial crop to be protected against insect pest through biotechnology. Thanks to a gene from a variety of the Bt bacteria, the NewLeaf Potato is resistant to the Colorado potato beetle.

Posilac® Bovine Somatotropin (Produced by Monsanto), Recombinant Bovine Somatotropin, (rBST)—rBST is a naturally occurring protein hormone in cows that induces them to produce milk. rBST improves milk production as much as 10 to 15 per cent and is now used by farmers whose herds represent over 30 per cent of the nation's cows. It was approved by the FDA in 1993.

Roundup® Ready Cotton (Produced by Monsanto)—Approved in 1996, Roundup Ready cotton tolerates both topical and post-directed applications of Roundup herbicide.

Roundup Ready® Soybeans (Produced by Monsanto)—Introduced in 1996, Roundup Ready soybeans allow growers to apply Roundup herbicide over the top during growing season. The result is dependable, superior weed control with no effect on crop performance or yield.

YieldGard® Insect-Protected Corn (Produced by Monsanto)—The YieldGard gene provides control of the European corn borer throughout the corn planting season.

NatureGard® Hybrid Seed Corn (Produced by Mycogen)—These corn plants express a protein toxic to European corn borer that will allow for less use of insecticides.

Chy Max® (fermentation-derived) (Produced by Pfizer, Marketed by Chr Hansen's)—Chy Max® is another version of chymosin, an enzyme that causes milk to coagulate. It is an advanced fermentation ingredient that is of higher purity, quality and activity than natural rennet.

VitroGraft® Grapevine Plants (Produced by Vinifera, Inc, a wholly owned subsidiary of Epitepe, Inc)—VitroGraft® grafted grapevine plants represent the highest-quality planting material available to the US grapevine industry. Rootstock and scion materials are in-house disease tested and grafted using proprietary green-grafting techniques.

Increased Pectin Tomatoes (Produced by Zeneca Plant Sciences)—Tomatoes that have been genetically modified to remain firm longer and retain pectin during processing into tomato paste.

Source: BIO Member Survey

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AGRICULTURAL BIOTECHNOLOGY PRODUCTS EXPECTED ON THE MARKET WITHIN SIX YEARS

Genetically Engineered Cotton Fiber (Produced by Agracetus, Inc.)—This biotech product will have enhanced fiber performance, reduce dye-shop pollution and improve textile manufacturing efficiency.

Liberty Link™ Soybean, Cotton Canola, Sugar Beet and Rice (Produced by AgrEvo®)—These Liberty Link™ crops will be available in Canada and/or the United States. Like Liberty Link™ corn, when used together with Liberty™ herbicide, they will allow farmers greater flexibility and environmental soundness in weed control.

Seed Link Corn (Produced by AgrEvo®)—These plants provide a more reliable pollination control system for corn seed production. The use of the Seed Link System eliminates the need for hand or mechanical detasseling.

Insect-Protected Corn (Produced by AgrEvo®/Plant Genetics System)—These plants express a protein toxic to various Lepidopteran pests, which allow less insecticide usage. Unlike insect-protected crops on the market today, the toxin in these plants binds to a different site in the insect's mid-gut, providing an advantage to insect-resistance management programs.

IMI™ Wheat Seed (Produced by American Cyanamid)—American Cyanamid is co-operating with universities, public and private laboratories and seed companies to develop wheat varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide contact and residual control of weeds common to wheat production, including ones not controlled by currently registered wheat herbicides.

IMI™ Rice Seed (Produced by American Cyanamid)—American Cyanamid is co-operating with universities, public and private seed companies to develop rice varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.

IMI™ Sugar Beet Seed (Produced by American Cyanamid)—American Cyanamid is co-operating with universities and seed companies to develop sugar beet varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.

BXN plus Bt Cotton (Produced by Calgene, Inc)—These cotton plants will require less chemical herbicide and insecticide to lower grower input costs and to achieve greater crop yield. Initial varieties are in field trials. Market introduction is planned for 1998.

Insect-Protected Tomatoes (Produced by Calgene, Inc)—These tomato plants will require less chemical insecticides to achieve higher yield.

High-Stearate Oil (Produced by Calgene, Inc)—High-stearate oil is an ingredient in margarine, shortenings and other food ingredients that would not require hydrogenation, thus reducing the expense.

High-Myristate Oil (Produced by Calgene, Inc)—This will be a less-expensive and more-abundant source of raw materials for soaps and detergents.

Medium Chain Fatty Acids/Medium Chain Triglycerides (Produced by Calgene, Inc)—This will be a less-expensive source of raw materials for high-performance lubricants, nutritional formulas and high-energy foods.

High Sweetness Tomato (Produced by Calgene, Inc)—Tomato plants that produce high-flavor tomatoes.

Disease-Resistant Strawberry (Produced by Calgene, Inc)—Strawberry plants that give improved crop yields and longer shelf life.

High Sweetness Strawberry (Produced by Calgene, Inc)—High quality fresh strawberries with improved flavor.

Genetically Engineered Fruits and Vegetables with Longer Post-Harvest Shelf Life (Produced by Agritope, Inc, a wholly owned subsidiary of Epitepe, Inc.)—Using ethylene-control technology, Agritope, Inc, has created delayed-ripening, longer-lasting tomatoes, raspberries and strawberries.

AquaAdvantage® Salmon, Tilapia, Trout, Flounder (Produced by A/F Protein)—The AquaAdvantage® salmon, tilapia, trout and flounder have the capability of growing from egg to market size (eight to 10 lb) in one to one and a half years. Conventional fish breeding techniques require three years to bring a fish to market. This new salmon could make fish more plentiful, decrease overfishing of wild salmon and lower consumer costs. A/F Protein expects to introduce the AquaAdvantage® salmon within four to six years to a public for whom salmon is an increasingly popular food.

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Ripening-Controlled Cherry Tomatoes (Produced by DNAP Holding Corporation)—Using the same technology as in its Endless Summer™ fresh market tomato, the company has developed cherry tomatoes with longer market life, improved flavor and better harvest traits through ripening control.

Seedless Mini-Melon (Produced by DNAP Holding Corporation)—This mini-melon is specially bred for its convenient single-serve size and flavor.

Sweeter Peas (Produced by DNAP Holding Corporation)—Sugar snap peas have been modified for sweeter flavor and higher yield by controlling the conversion of sugar to starch using Transwitch® technology. Pea plants are currently in field evaluations.

Firmer Peppers (Produced by DNAP Holding Corporation)—This sweet pepper has been modified using Transwitch® technology to remain firmer after harvest. Pepper plants are currently in field evaluations.

Sweeter Peppers (Produced by DNAP Holding Corporation)—This pepper has been modified to be sweeter and tastier by overexpressing a gene for sweetness. Pepper plants are in early stages of seed increase and field evaluation.

Ripening-Controlled Bananas and Pineapples (Produced by DNAP Holding Corporation)—Using the same ripening control technology as in its Endless Summer™ tomato, the company is developing banana and pineapple varieties with extended market life.

Strawberry (Produced by DNAP Holding Corporation)—The company is improving the market life of fresh strawberries by using Transwitch® technology to keep fruit firmer after harvest and adding genes to resist disease.

High-Solids Potato (Produced by Monsanto)—Monsanto has developed a higher-solids (or starch content) potato by introducing a starch-producing gene from a soil bacteria into a potato plant. With the reduction in the percentage of water in the genetically improved potato, less oil is absorbed during processing, resulting in a reduction of cooking time and costs, better-tasting french fries and an economic benefit to the processor.

Roundup Ready® Canola (Produced by Monsanto)—Roundup Ready canola allows growers to apply Roundup® herbicide over the top of the crop during the growing season, for superior weed control with enhanced crop safety.

Roundup Ready® Sugar Beets (Produced by Monsanto)—Roundup Ready sugar beets are tolerant of Roundup Ready® herbicide and provide growers with a new weed-control option while the crop is growing.

Roundup Ready® Corn (Produced by Monsanto)—Roundup Ready corn allows over-the-top applications of Roundup® herbicide during the growing season for superior weed control.

New-Leaf® Y Insect- and Virus-Protected Potatoes (Produced by Monsanto)—These potatoes protect themselves against the Colorado potato beetle and the potato virus Y.

Second-Generation Bollgard® Insect-Protected Cotton (Produced by Monsanto)—This cotton controls insect pests, like the original Bollgard cotton, but uses a different mode of action to help growers manage insect-resistance concerns.

High-Stearate Soy Oil (Produced by Monsanto)—This is a functional oil with healthier properties for margarines and shortenings. High-stearate oil requires no hydrogenation and contains no trans-fatty acids, which increase cholesterol.

Bt Sunflower, Soybeans, Canola and Wheat (Produced by Mycogen Corp.)—These crops will express a protein toxin providing protection against various caterpillar and beetle pests.

Fresh Market Tomato (Produced by Zeneca Plant Sciences)—Zeneca is modifying the tomatoes for enhanced flavor, color and increased antioxidant vitamin content.

Banana (Produced by Zeneca Plant Sciences)—Zeneca is developing an inherent resistance to Black Sigatoka and modifying ripening characteristics in bananas. This will reduce the need for chemical fungicides as well as improve the agronomics of production and the quality to the consumer.

Modified Lignin in Paper Pulp Trees (Produced by Zeneca Plant Sciences under separate agreements with Shell Forestry and Nippon Paper)—By making lignin easier to remove from cellulose—the primary ingredient in paper—paper makers can make high quality paper with less energy and bleaching, which results in benefits to both the paper processor and the environment.

Source: BIO Member Survey

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BIOPESTICIDES, HERBICIDE RESISTANCE AND NATURAL PROTECTIONS FOR PLANTS

BIOPESTICIDES

Several biopesticides¹ are in use today. *Biopesticide products* are based on natural agents such as microorganisms and fatty acid compounds. They are *toxic only to targeted pests* (such as the European corn borer) and do not harm humans, animals, fish, birds and beneficial insects. In addition, because biopesticides act in unique ways, they *can control pest populations that have developed tolerance to chemical pesticides*.

One of the most common microorganisms used in biologically based pesticides is the *Bacillus thuringiensis*, or Bt bacterium. Several of the proteins produced by the Bt bacteria, principally in the coating the bacteria forms around itself, are lethal to individual species of insects. By using Bt bacteria in pesticide formulations, target insects can be eliminated without relying on chemically based pesticides.

It is also possible to use pheromones in pest control. Pheromones are naturally occurring substances that insects produce to attract mates. *In pest control, pheromones are used to attract insects away from crop plants*. In recent years, for example, pheromone-based traps were used to control fruit fly infestations in California. European corn borers, one of the most prevalent pests, costs the nation \$1.2 billion in crop damage each year.

HERBICIDE RESISTANCE

Planting conditions good for crop plants will also sustain unwanted weeds that can reduce crop yield. To prevent this, herbicides are sprayed on crops. Often, herbicides must be applied several times during the growing cycle, at great expense to the farmer and possible harm to the environment.

Using biotechnology, it is possible to *make crop plants tolerant of specific herbicides*. When the herbicide is sprayed, it will kill the weeds but have no effect on the crop plants. *This lets farmers reduce the number of times herbicides have to be applied and reduces the cost of producing crops and damage to the environment*.

NATURAL RESISTANCE TO PESTS AND VIRUSES

We can, today, transplant the genetic information that makes a given bacterium—such as the Bt bacterium—lethal only to a specific insect (but not to humans or animals) into plants on which that insect feeds. *The plant that once was a food source for the insect now kills*. This process, which has no effect whatsoever on humans or other species, means that it becomes less necessary to spray crops with chemical pesticides to control infestations.

BIOPESTICIDE PRODUCTS CURRENTLY ON THE MARKET

Laginex™ Bioinsecticide (Produced by AgraQuest, Inc)—This product is effective for controlling a wide range of mosquito larvae in rice, wetlands and other bodies of water.

Disease Free Kleentek™ (Produced by Crop Genetics International)—This product increases yield of sugar per acre.

Spod-X™ (Produced by Crop Genetics International)—Spod-X™ uses a naturally occurring insect virus to control the beet armyworm. The beet armyworm is becoming resistant to many chemical insecticides. Spod-X™ is safer to use and better for the environment.

Aspire™ (Produced by Ecogen)—Aspire™ is a biofungicide used to protect fresh produce from post-harvest rot. It is used on citrus, pome fruits, berries and grapes. The active ingredient is a naturally occurring yeast that is harmless to all nontargeted organisms.

Condor® Bioinsecticide (Produced by Ecogen)—This product is effective against the tobacco budworm, cotton bollworm, the soybean looper, velvetbean caterpillar, green clover worm, gypsy moth and spruce budworm.

Cutlass® Bioinsecticide (Produced by Ecogen)—This is a broad-spectrum bioinsecticide effective against the beet armyworm, cabbage looper, diamondback moth, cabbage webworm and imported cabbageworm.

Otinem® Insecticide, Bee-scent® and No-Mate® (Produced by Ecogen).

AQ-10® (Produced by Ecogen)—AQ-10® is a biofungicide that protects crops from powdery mildew. It is used on strawberries, grapes, tomatoes, cucurbits and ornamentals. It reduces the use of conventional fungicides.

¹ A biopesticide is any material of natural origin used in pest control derived from living organisms, such as bacteria, plant cells or animal cells.

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Mattech® (Produced by Mycogen)—Controls broad spectrum of caterpillars in vegetables, field crops, nuts, grapes, turf, stored grain, and ornamental and nursery crops.

MVP® (Produced by Mycogen)—This product is used on tree fruits and nuts, vines, cotton and vegetables to control leaf-eating caterpillar pests.

M-Peril™ (Produced by Mycogen)—This product is used on corn to combat the European corn borer.

M-Pede™ (Produced by Mycogen)—M-Pede™ is used on fruits, vegetables, grapes and ornamentals to resist soft-body insects and powdery mildew.

DeMosstm (Produced by Mycogen)—This product is used on roofs, buildings, sidewalks and greenhouses to resist moss, algae and lichens.

Thinex® (Produced by Mycogen)—This product is used for blossom thinning in apples, pears and fruits.

M/C® (Produced by Mycogen)—MC is used on vegetables to control various caterpillar pests.

Source: BIO Member Survey

BIOPESTICIDE PRODUCTS EXPECTED ON THE MARKET WITHIN THREE YEARS

QST 153 Biofungicide (AgraQuest, Inc.)—For diseases of grapes, vegetables and fruit (downy mildews, bunch rot, gray mold and brown rot).

QST 177 Biofungicide (AgraQuest, Inc.)—For diseases of grapes, other fruits and vegetables, turf and ornamental (powdery mildew, gray mold, scab and damping off).

QST 776 Insect Repellent (AgraQuest, Inc.)—Natural product for repelling mosquitoes, ticks, and other biting insects.

Ecologix™ Cockroach Bait (Produced by Dominion Biosciences)—This is the first commercial product developed from a unique insect growth regulator technology. It is highly effective in eliminating insect populations, yet completely nontoxic to users, pets and the environment.

Leone™ Biofungicide (Produced by Dominion Biosciences)—This product controls a number of plant diseases by relying on highly active, antimicrobial predator bacteria. These naturally derived biochemicals offer a new mode of action for effective and safe control of disease-causing micro-organisms.

Crymax™ (Produced by Ecogen)—Crymax™ is a genetically engineered bioinsecticide that is very effective against a broad range of pests. It will be used on vegetables, trees, nuts and vines.

EG7826™ (Produced by Ecogen)—This will be a genetically modified insecticide that will control the fall armyworm, a major insect pest affecting sweet corn.

Scythe™ Herbicide (Produced by Mycogen)—This is used for horticulture and landscape management to combat a broad spectrum of weeds.

Source: BIO Member Survey.

BT-BASED AND OTHER BIOLOGICAL CONTROL AGENTS

A number of products are in development that will control insects as well as conventional insecticides, thereby reducing the use of these products.

Bt technology is used to develop and specially formulate a line of biotoxin and fatty acid-based products for field testing in the poultry and livestock industries.

Mycogen, Ecogen and Ciba Geigy Ag Group are three of the companies developing these products.

Biculovirus Insecticides (Produced by American Cyanamid)—These products express insect-specific toxins and control Lepidopteran pests at levels similar to chemical insecticides.

Agree® (Produced by Ciba Geigy Ag Group—Ciba Crop Protection)—This is a Bt-based bioinsecticide designed to control pests that affect tobacco, corn and soybean plants.

Design® (Produced by Ciba Geigy)—Design® is a Bt-based bioinsecticide for cotton and soybeans.

Exhibit® (Produced by Ciba Geigy)—Exhibit® is a parasitic nematode for control of insects on ornamental plants and turf.

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M-Press (Produced by Mycogen)—This product will be used to control the fall army worm in sweet corn and other vegetable crops.

Source: The Biotechnology Industry Organisation

INSECT-, VIRUS- AND HERBICIDE-RESISTANCE PLANTS UNDER DEVELOPMENT

Herbicide-Tolerant Plants (Produced by American Cyanamid)—American Cyanamid is working within universities, public and private laboratories and seed companies to develop a number of crop plants to tolerate imidazolinone herbicides. This tolerance lets farmers use flexible, environmentally friendly herbicides while achieving cost-effective contact and residual control of weeds.

Crops under development for tolerance to imidazolinone herbicides

Wheat

Rice

Sugar beets

Herbicide-Tolerant Plants (produced by Monsanto)—Monsanto has genetically modified a number of crop plants to tolerate its Roundup® herbicide. This natural tolerance lets farmers reduce herbicide applications while achieving cost-effective broad-spectrum weed control using a product well known for its favourable environmental characteristics.

Crops tolerant to Roundup® Herbicides

Canola/Oilseed Rape

Corn

Sugar beets

Bt Cotton, Alfalfa, Canola and Sunflower (Produced by Mycogen)—Plants that express a protein toxic to various insect pests, which will allow for less use of insecticides.

HOW AGRICULTURAL BIOTECHNOLOGY IS REGULATED

Since combining specific genes from donor and host plants does not alter the basic nature of the host plant, the result of genetic modification is predictable and can be carefully controlled. As with any new variety of food, the developers test extensively for safety, quality and other factors.

The Food and Drug Administration (FDA) is responsible for approving the safety of all foods and new food ingredients. In addition, all producers are required to ensure the safety and quality of anything they introduce into the food supply.

The US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) impose safety requirements and/or performance standards on the development of pesticides, herbicides and genetically modified test crops. Examples of tests include crops with improved disease resistance and animal vaccines produced from biotech microorganisms.

The EPA regulates the use of chemicals, including pesticides in the environment. With this authority, EPA must approve any field test of biotech products with new properties.

The FDA may require that genetic modifications that significantly alter the nutritional value of the host food, use genetic material from outside the traditional food supply or use known allergens be subject to strict premarket testing and regulatory oversight.

The FDA also requires that any genetically modified food product that significantly alters the host food's nutritional value or uses material from a known allergen be clearly labeled. For example, any product that used a gene from a peanut, which is a potential allergen, would be subject to testing and labeling requirements. The FDA also has the authority to order unsafe products off the market.

WEDNESDAY 15 JULY 1998

Present:

Gallacher, L.	Moran, L.
Gisborough, L.	Reay, L. (Chairman)
Grantchester, L.	Wade of Chorlton, L.
Jopling, L.	Willoughby de Broke, L.

**Memorandum by the Ministry of Agriculture, Fisheries and Food, the Department of Health,
Scottish Office, Welsh Office and Northern Ireland Office**

INTRODUCTION

1. The Government aims to protect public health in relation to food by promoting and enforcing high standards of food safety as a matter of paramount importance at all stages in the production, processing and supply of food. It is committed to openness and transparency in the way it works and consults fully with all interested groups affected by its activities. The Government recognises the many potential benefits that genetic modification offers to agriculture and ultimately to consumers. Examples include a reduction in the quantities of herbicides through the development of herbicide tolerant plants, the production of insect resistant or disease resistant crops and the production of medicinal products using animals. Consumers stand to gain from foods that are more nutritious, tastier, more plentiful and cheaper. Therefore, provided that all GM foods have been thoroughly assessed for safety, the Government believes that consumers should be allowed to choose whether to purchase them or not. For this to be possible all foods containing GM materials must be clearly labelled. The recently agreed EC Regulation on the labelling of GM soya and maize will help to make sure this requirement is met. The only GM foods currently on the market are a vegetarian cheese made using the enzyme chymosin obtained from a GM organism, a GM tomato paste, and foods containing ingredients from GM soya and maize. Oils produced from GM oil seed rape is likely to be the next product on the market. The Government will continue to ensure that GM products are regulated in an appropriate manner and that the regulatory framework is kept under regular review.

GMO LEGISLATION

2. There is a comprehensive UK regulatory framework, based on EU legislation, covering all stages of work with genetically modified organisms (GMOs) designed to protect human health and the environment. This consists of the EC Contained Use Directive (90/219) dealing with all aspects of the development of GM Micro Organisms prior to their release into the environment, the EC Deliberate Release Directive (90/220) which lays down environmental safety controls for releases and marketing for GMOs and the Novel Foods and Novel Food Ingredients Regulation (258/97) which covers all aspects of the use of GM technology for the production of foods. In Great Britain, the competent authorities for the first two Directives are the Health and Safety Executive and the Department of the Environment, Transport and the Regions who will deal with their respective Directives in their memoranda. The Novel Foods and Novel Food Ingredients Regulation and associated controls are described in more detail in the following paragraphs.

GENETICALLY MODIFIED FOODS

The EC Novel Foods Regulation 258/97

3. The EC Novel Foods Regulation (258/97) came into force on 15 May 1997, following extensive consultation between Member States. The then UK Government also conducted a series of consultations with industry and consumer groups at various stages of the Regulation's development. The Regulation established an EU wide pre-market approval system for all novel foods, that is foods which have not hitherto been used for human consumption to a significant degree in the EU before, including foods containing or produced from genetically modified organisms (GMOs). Where an application is for a food or food ingredient that contains or consists of a GMO, the application will also need to include an environmental risk assessment in line with the requirements of Directive 90/220/EEC. The Regulation also lays down general labelling requirements (see paragraph 9).

4. The Novel Foods Regulation is enforced in the UK by The Novel Foods and Novel Food Ingredients Regulations 1997, which lay down offences and penalties. These also designate the Minister of Agriculture, Fisheries and Food and the Secretary of State for Health, acting jointly, as the competent food assessment authority in the UK. The Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 make provisions for charges to be set for assessment of novel foods and novel food ingredients applications. DETR and the Advisory Committee on Releases into the Environment (ACRE) will be consulted on the environmental risk assessment, under arrangements set out in a Memorandum of Understanding.

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Safety Assessment of Novel Foods

5. In the UK we have considerable experience of assessing the safety of novel foods, including those produced using genetic modification, stretching back over some 10 years. These assessments are carried out by the Advisory Committee on Novel Foods and Processes (ACNFP), a body of independent experts whose expertise is acknowledged world-wide. The safety assessment is based on the concept of substantial equivalence which involves a comparison of a GM food with its conventional equivalent and a detailed examination of any differences. Where there is no equivalent, all aspects of the novel food are examined in detail. This approach has been endorsed by the World Health Organisation and is widely used by regulatory authorities around the world. Applications currently under consideration by the Committee are for processed products from two GM cotton seeds (cotton seed oil) (one developed to be insect protected and the other to be herbicide tolerant), one GM maize (developed to be both insect protected and herbicide tolerant) and one GM potato (developed to be insect protected).

6. The ACNFP includes amongst its members an ethicist and a consumer representative. More general issues, including labelling, are referred as necessary to the Food Advisory Committee (FAC). This Committee has a broader membership than the ACNFP consisting of those with backgrounds in food, enforcement, advertising standards, consumer affairs, manufacturing and retailing, and academia and is therefore well equipped to deal with any matters requiring a wider perspective.

7. The ACNFP has for some time published the agendas and a note of the outcome of each of its meetings as well as detailed reports of its assessments and an annual report (copy of 1996 report attached). [*not printed*]. More recently however it has begun to publish the minutes of its meetings. It has also been agreed that papers discussed at the meetings will be made available on request and a Newsletter will be published. It has also decided to hold open meetings on topics of wider interest so as to provide as much opportunity as possible for people to learn about, and contribute to, the issues that it is dealing with. In this way, it is hoping to encourage interested parties, including members of the public, to make more of an input into its deliberations.

8. One such meeting of a subgroup of the ACNFP was recently held to examine the possibility of setting up post-market surveillance arrangements for monitoring any long term effects of novel foods on public health as an additional safeguard. This was also attended by industry, pressure groups and consumer observers. The meeting proved extremely useful and a number of ideas emerged which are in the process of being followed up.

Labelling of GM Foods

9. The Government is determined that all foods which contain GM ingredients should be clearly labelled so that consumers know what they are buying. The Novel Foods Regulation requires specific labelling when a food is judged, on the basis of a scientific assessment, not to be equivalent to an existing food. Food will also require labelling if there are any health or ethical concerns or if it contains a GMO. The EC has recently adopted a Regulation laying down detailed rules for the labelling of GM soya and maize, which will come into force in September. This requires all foods containing ingredients produced from Monsanto's GM soya and Novartis' GM maize to be labelled except when neither protein nor DNA resulting from genetic modification is present. This is likely to set a precedent for the way all future GM foods will need to be labelled. The Regulation incorporates a number of requirements put forward by the UK during its Presidency of the EU.

Segregation

10. A number of organisations have called for GM material, such as soya beans, which are produced outside Europe, to be segregated from conventionally produced products. However, the Government cannot insist on this as a condition of import as GM soya has been cleared on safety grounds by all member states and such a requirement would therefore contravene the rules of the World Trade Organisation. In recognising these constraints, the Government has nevertheless been considering what can be done to help companies who wish to obtain supplies of non-GM soya to be able to do so. With the co-operation of the Canadian and US authorities, a list of suppliers and distributors of non-GM soya has recently been published by MAFF and placed on the Internet.

R&D

11. MAFF has a sizeable (>£1 million in financial year 1998-99) and expanding programme of research on the safety of Novel Foods and Releases of GMOs into the Environment. The objective of this programme is to provide information needed to safeguard the consumer and the environment from any risks associated with the consumption of novel foods and the release of food related GMOs. Research projects to date have fallen into the broad areas of analysis, labelling and risk evaluation and have covered the genetic stability of crop and

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model plant species after transformation, gene transfer and the implications for safety of novel gene expression. Projects include work on:

- Methods to detect of GMOs in processed and unprocessed foods.
- Development of databases on genes that have been introduced by genetic modification of crops intended for food use.
- Development of methods to predict the allergenic potential of genetically modified foods and novel protein products.
- Investigation of the transfer of genetic material to gut microflora from ingested GM micro-organisms.
- Investigation of *Agrobacterium* as a vehicle of gene escape.
- Investigation of the stability of expression and inheritance of transgenes.
- Investigation of the effect of background genotype on transgene expression.
- Increasing the public's understanding of biotechnology.

GENETICALLY MODIFIED CROPS

Herbicide Tolerant and Pest Resistant Crops

12. In July 1997, MAFF issued a consultation paper called "Weed Control on the Farm: Management of Genetically Modified Herbicide Tolerant Crops" and invited comments from interested parties. Virtually everyone who responded agreed that GMHT crops must be properly managed. The comments—which are available for reading in MAFF's Main Library—fell mainly into three categories; support for an industry code of practice; support for a moratorium until MAFF-funded research on possible risks to the agricultural environment from the release of GMHT crops was complete; or demands for an outright ban on GM crops. The Government is currently finalising its views and expects to make an announcement soon. It has however received advice that there are no legal powers which would allow the Government to impose a moratorium or a ban on the use of these crops.

R&D

13. In 1990 MAFF started a programme of research to look at the possible risks to the agricultural environment from the release of genetically modified organisms. Over £3.5 million has been committed to the programme and, to date, results have not indicated any risks to the agricultural environment from the release of GMOs. In 1997, new research on the release of herbicide tolerant crops was commissioned. The research, with a total budget of over £500,000, is due to be completed in 2000. Projects include work on:

- Studies of the local and regional scale movement of an oil seed rape transgene.
- The role of bees in pollen transport between sites.
- Consequence analysis of the impact on agriculture and the environment of the release of herbicide tolerant oil seed rape.
- Impact of changes in patterns of herbicide usage on the environment and biodiversity.
- Risk assessment of transgene movement.
- Frequency and impact of transgene movement by pollen to weed species.

National Listing and plant breeders' rights

14. The Seeds (National Lists of Varieties) Regulations 1982 as amended implement EC Directive EC 70/457 and EC 70/458 and provide that varieties of the main agricultural and horticultural species must be on the UK National list or the EC Common Catalogue before their seed can be marketed. Varieties are grown in official tests and trials, normally for two years, to establish that they are Distinct, Uniform and Stable (DUS) and have value for cultivation and use (VCU), before they are Nationally Listed. This system underpins the quality of new agricultural crops being introduced into the UK.

15. If a plant variety is genetically modified the quite separate stringent controls under part VI of the Environmental Protection Act 1990 and Regulations made under it, which implement Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, also apply. Under these controls, MAFF cannot undertake official tests and trials unless a consent to release or market has been issued by the Secretary of State or by another Member State's competent authority. Moreover, GM plant varieties will not be added to the National List until all the necessary safety and environmental clearances to permit marketing are in place.

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16. At present, there are no GM varieties on the UK National List, though MAFF has received applications for addition of GM varieties of sugar beet (five varieties), maize (one variety) and oilseed rape (14 varieties). These are at varying stages in National List tests and trials and the point at which they might be available commercially varies from application to application. The earliest point at which seed of GM varieties (two spring oilseed rapes) could be available for commercial planting is spring 1999.

17. MAFF is also responsible for the administration of UK plant breeders' rights. These are an intellectual property right, akin to patents, but designed specifically to protect plant varieties. Varieties entered for plant breeders' rights are also tested for Distinctness, Uniformity and Stability. MAFF is currently considering 22 applications for plant breeders' rights in respect of gm oilseed rape varieties (nine of these are combined National List/plant breeders' rights applications and 13 are for plant breeders' rights only).

Pesticide approvals

18. Herbicides are controlled, under British and EC law, as pesticides. Under the pesticides approvals process, no pesticide may be advertised, sold, supplied, stored or used unless Ministers have approved that pesticide and consented to that activity. Applicants for pesticide approval must show that their products are effective, humane and pose no unacceptable risks to human beings, non-target species or the wider environment. Various statutory conditions are attached to pesticide approvals to protect human and environmental safety. These include the crop on which the pesticide may be used, maximum dose rates and the maximum number of applications that can be made. In seeking any extension of authorisation of a pesticide to include herbicide tolerant crops necessary safety and efficacy data would have to be supplied by the applicant. The normal considerations of human and environmental safety would determine whether such an application would be granted. At present there are no approvals for the use of herbicides on GM herbicide tolerant or pest resistant crops.

GENETICALLY MODIFIED FARM ANIMALS

Cloning

19. Research on cloning (nuclear transfer) requires a licence from the Home Office under the Animals (Scientific Procedures) Act 1986. Regulations to control the commercial cloning of animals could be made under the Animal Health and Welfare Act 1984. Cloning was considered acceptable by the 1995 "Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals" (the Banner Committee). The Farm Animal Welfare Council has been asked to consider the possible implications of cloning for the welfare of farmed livestock, and whether any further moral or ethical issues need to be addressed. Human cloning is the concern of the UK Human Embryology and Fertilisation Authority and the Human Genetics Advisory Commission.

Other Genetic Modification Involving Farm Animals

20. MAFF's policy on genetic modification of farm animals is guided by the recommendation of the Banner Committee report. The report recognised that existing regulations mean that genetically modified animals are likely to be more thoroughly protected than those produced by conventional means.

21. Genetic modification of animals is a regulated procedure under the Animals (Scientific Procedures) Act 1986 and requires a licence from the Home Office. The Genetically Modified Organisms (Contained Use) Regulations 1992 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992, both as amended, cover the storage, use, release for research purposes, marketing, transportation and destruction of genetically modified animals.

R&D

22. MAFF has been the major supporter of work on cloning and has funded research at the Roslin Institute on cloning since 1991 at a cost of over £2 million to date. An additional £1.3 million has been spent on research into the problem of oversized offspring—a syndrome known to occur following *in vitro* fertilisation. MAFF funded the work because of its potential to contribute towards the genetic improvement of livestock. Following the scientific breakthrough leading to Dolly the cloned sheep, MAFF is now focussing research on improving the efficiency of cloning. Current spend on this by MAFF is £120,000 per year.

23. In the UK there is a view that the benefits to medicine of producing pharmaceuticals in milk, or of xenografts, may justify genetic modification of animals. In addition, much useful information on human (and some animal) diseases is obtained by creating transgenic animal models of diseases. MAFF is considering one

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such project on scrapie. However, with present knowledge, many people feel that research to improve livestock performance through genetic modification is not justified. MAFF does not fund such research.

ANIMAL FEEDINGSTUFFS

24. The European Commission is expected to propose shortly a new Directive covering novel feed materials. This will provide an opportunity for a specific assessment of the implications of feeding GM material to animals. Currently in the UK the ACNFP considers the impact of such feeding on food for the ultimate consumer. A new Advisory Committee of Animal Feedingstuffs will consider GM feed materials when it is set up later this year, liaising closely with the ACNFP.

CONSUMER EDUCATION

25. An important consideration for consumers when deciding whether to purchase GM foods is an awareness of what the technology involves. MAFF has always recognised the importance of providing information about this and first produced a Foodsense booklet on genetic modification and food in 1995. Last year we commissioned and part funded a mobile exhibition on food biotechnology organised by the Science Museum. We are currently considering a number of further initiatives for disseminating information about the technology which we hope to put in place later this year. In the meantime we are actively supporting a public consultation on biotechnology which was announced by the Minister for Science and Technology last November. This is an important mechanism for identifying public concerns about the technology.

4 June 1998

Memorandum by the Department of the Environment, Transport and the Regions, and on behalf of The Scottish Office and The Welsh Office¹

1. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION OF RESEARCH, RELEASE INTO THE ENVIRONMENT, AND NOVEL FOODS AND THEIR LABELLING AT EUROPEAN UNION LEVEL

1. INTRODUCTION

1. The regulation of all research releases of genetically modified organisms (GMOs), including those intended for use in agriculture, is governed in the EC through Directive 90/220/EEC, the Deliberate Release into the Environment of Genetically Modified Organisms (the "Directive"), which came into force in October 1991. In addition, the Directive establishes a single entry point to the Community market for certain products containing genetically modified organisms (GMOs).

2. OBJECTIVE OF THE DIRECTIVE

2. The Directive is based on the precautionary principle: Member States must take measures to ensure that adverse effects on human health and the environment from the release and marketing of GMOs are avoided. Development must proceed on a step-by-step basis, and proposals to release and market GMOs are assessed case-by-case. Plants intended for agricultural use are normally developed in glasshouses before being tested in different environments and at increasing scale. The organisms covered by the Directive are defined in terms of specific techniques of modern biotechnology.

3. In order to achieve appropriate controls to implement its objective, the Directive establishes a prior consent regime for all releases and marketing. An application must be submitted to a competent authority; the application contains detailed information about the GMO and, if appropriate, about the potential receiving environment and intended risk management measures. In addition, the application has to contain an assessment of the risks to human health and the environment. The Directive does not lay down the principles or method for the risk assessment, or specify the type of effects that have to be taken into account. However, the risk assessment necessarily builds on the knowledge of the parent organism and the results from previous trials. Such results will be obtained through monitoring, but details of monitoring requirements are not laid down in the Directive.

4. The requirements of the Directive are such that consents for research releases and marketing of GMOs must be granted provided that competent authorities consider that adverse effects will not occur, or will be avoided.

¹ The Department of Health and the Department of Trade and Industry were also asked for evidence, but they wished to add nothing to the memoranda by the Ministry of Agriculture, Fisheries and Food and the Department of the Environment, Transport and the Regions. The Health and Safety Executive submitted a separate memorandum, for which see pages 347-349. The Health and Safety Executive also submitted a separate memorandum on behalf of the Scottish Office, for which see pages 350-351.

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3. OPERATION OF THE DIRECTIVE

1. Research releases

Procedures

5. Notifications of proposals to carry out research releases are submitted to the competent authority in the Member State in which the release is to be carried out, and a summary of the proposal is circulated to the Commission and to the other Member States, which have 30 days within which to comment. Decisions on releases are taken at the national level, within 90 days of the receipt of the notification. A competent authority can stop the clock in order to seek further information from the applicant.

Experience

6. In the light of experience and the rapid increase in the number of research releases during the first two years of operation of the Directive, the UK and France submitted requests to apply simplified procedures. These were adopted at Community level in 1994. They have the effect of allowing an applicant to apply for a single consent to cover an entire development programme of a modified plant. All Member States, except Greece and Luxembourg, implemented this first simplified procedure and it is widely used. The UK, the Netherlands, France and Germany subsequently submitted further requests for simplified procedures, but the Commission has not taken these forward.

7. In addition, the Directive has been adapted to technical progress to tailor better the information requirements for research releases of genetically modified plants.

8. The Directive has operated well as regards control of research releases. More than 1,100 such releases have been carried out in the EC since the Directive came into force in 1992, compared with over 8,000 worldwide. Most releases outside the EC have taken place in the USA and Canada but increasingly releases are being carried out elsewhere in the world, notably in Argentina and China. The majority of releases have been of crop plants. Details of the types and numbers of releases are at Appendix 1.

2. MARKETING OF GMO PRODUCTS

Procedures

9. Before a GMO product can be marketed in the EC, an application must be submitted to the competent authority in the Member State in which the product is first intended to be marketed. Again, the notification must contain detailed information about the GMO and a full human and environmental risk assessment. At this stage, the impact on a specific receiving environment in the risk assessment is often inappropriate since an approved product can be marketed throughout the Community. Risk management measures will not usually be necessary providing that previous trials have demonstrated that adverse effects are unlikely to occur. If the competent authority considers that consent to market the product should be given, it forwards the notification to the Commission within 90 days.

10. Other competent authorities have 60 days to review the notification after it has been circulated by the Commission. Providing no Member State objects during this period, the competent authority in the originating Member State must issue the consent. However, should any Member State object, the Commission has to submit a proposal to a regulatory committee. If, then, a qualified majority in the regulatory committee is in favour of the proposal, and the proposal is to consent to the marketing, the Commission must issue a decision requiring the Member State to grant the consent. If there is no qualified majority, the Commission has to submit a proposal to the Council which can amend the proposal only by unanimity. Should the Council fail to act within three months, the Commission is required to adopt the measures in the proposal. This is known as the IIIa procedure. The Directive does not prescribe time periods for the submission of the proposal by the Commission to the regulatory committee or to the Council, or for the issuance of the decision by the Commission.

11. The directive was amended to technical progress for a second time in 1997 by introducing a requirement that if a product is known to contain GMOs, it must be so labelled, and if there is good reason to believe that a product contains GMOs, that the product be labelled "may contain GMOs". There were two reasons for this: first, to take account of public concerns about the labelling of GMO products; and second, in order to comply with the 1997 EC Regulation on Novel Foods and Novel Food Ingredients, manufacturers and retailers need to have adequate information about any crops intended for processing or direct sale as foods.

Experience

12. Since the Directive came into force, 26 notifications to market GMO products have been submitted in the EC. Three of these were of vaccines, one was a microbiological kit to test for the presence of antibiotics in milk, one was for a carnation, and the remainder were of crop plants (details at Appendix 2). Only the notification

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to market the flower was uncontroversial and did not need to be referred to the regulatory committee. Nine consents have been issued to date and the remainder are in the pipeline. Of the four notifications submitted in 1995, only two have so far received consent; of the seven submitted in 1996, only three consents have been issued; and all five submitted last year are still under consideration. All the outstanding notifications concern crop plants.

13. One or more Member States have raised objections to proposals to market a GMO product for three major reasons. First, some Member States objected if the applicant did not propose to label; this situation has been relieved by the 1997 technical amendment of the Directive to require labelling. Second, some Member States considered that the environmental risk assessment for crop plants genetically modified to be tolerant to certain herbicides should take into account the impact on herbicide use, a view not shared by the Commission. Third, until the adoption of the Novel Foods and Food Ingredients Regulation, those Member States that considered that the Directive covered the use of a product as a food were often not satisfied with the extent of information provided. It has come to be accepted that notifications submitted under the Directive should include a full assessment of the product for a particular use. Exemptions from the Directive apply only to GMO products covered by Community legislation with a similar environmental risk assessment. To date, the only such legislation is that governing novel foods, animal feedingstuff additives, and medicinal products for human and veterinary use.

14. This specific product legislation requires that necessary consultations are carried out with the bodies set up by the Community or the Member States under the Directive. However, the legislation does not provide for a formal mechanism by which the results of consultation are taken into account in the final decision. No practice has as yet been developed as only one application, for a cholera vaccine, has to date been submitted under this product legislation.

15. Proposals to amend other product legislation governing seeds and animal feeds are currently under discussion, but for the foreseeable future, such products will continue to be subject to the Directive.

4. COMMISSION PROPOSAL FOR AMENDMENT OF THE DIRECTIVE

16. The Commission's proposal for amendment seeks to address most of the concerns that have been raised in the six years since the Directive came into force. The main changes are that the amendment:

- allows the Commission to consult a committee to advise on the ethical implications of biotechnology on general matters which may raise ethical concerns;
- clarifies certain terms and the scope of the risk assessment and includes the principles on which the risk assessment should be based;
- introduces, on the basis of experience and knowledge, two categories of research releases for which those in the lower risk category are decided within 30 days;
- removes the possibility for Member States to apply for simplified procedures for research releases;
- exempts trial releases from the Directive if they are covered by other Community legislation;
- introduces time periods within which the Commission has to submit proposals on marketing notifications to the regulatory committee and to Council, and within which a competent authority must issue a consent following the Commission's decision;
- establishes a regulatory committee procedure which would allow any draft decisions which reach the Council to be amended by unanimity or rejected by simple majority;
- introduces a seven year time period for consents to market and a new procedure for renewing marketing consents;
- requires monitoring after a marketing consent has been granted;
- introduces a simplified procedure for certain marketing cases;
- introduces a mediation period in which Member States can seek to resolve differences in views about the advisability of marketing a specific GMO product;
- requires the Commission to seek the opinion of the Community-level scientific committee on any case which might cause risk to human health or the environment but without specifying the process by which the opinion will be taken into account or the time frame for consideration by the committee;
- requires the Commission to consult the public on marketing notifications.

17. The UK has expressed concern about the current regime, and in particular about delays in decision-making as regards marketing applications, shortcomings in the regulatory committee procedure, and the limitations to addressing public concerns. The UK is generally supportive of the Commission's proposal but considers that some changes and clarification are necessary. The UK is to take the Commission proposal forward during its Presidency in an orientation debate at the June Council of Environment Ministers.

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5. REGULATIONS OF NOVEL FOODS AND THEIR LABELLING

18. MAFF is the lead Department for novel foods and will cover regulation and labelling in its submission.

2. APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

19. The UK was one of the first countries in the world to introduce controls on modern biotechnology when it introduced regulations covering GMOs in 1978. Reflecting the state of the technology at that time, the controls only governed contained uses of GMOs and potential human health effects. By the mid-1980s, the first small releases were being carried out and increasing attention was being given to potential environmental effects. In 1989, the Royal Commission on Environmental Pollution (RCEP) reported on the release of GMOs into the environment, when they recommended a prior consent regime and public disclosure of information. Virtually all the RCEP's recommendations were implemented in the UK. The requirements imposed by the Directive were congruent with these recommendations.

20. Part VI Environmental Protection Act 1990 (the Act) and the GMO (Deliberate Release) Regulations 1992, 1995 and 1997 implement the Directive in Great Britain. Parallel legislation has been in place in Northern Ireland since 1994. The effect of the legislation is that no GMO can be released without the consent of the Secretary of State; in England, this is the Secretary of State for the Environment, Transport and the Regions; in Scotland, the Secretary of State for Scotland; and in Wales, the Secretary of State for Wales. Before a consent can be issued, the Secretary of State has to have the agreement of the Health and Safety Executive which considers human health effects. In cases concerning agricultural applications, the relevant Secretary of State acts jointly with the Minister of Agriculture, Fisheries and Food. The Department of the Environment, Transport and the Regions consults with other interested departments on all applications under a Memorandum of Understanding.

21. Under the Act, the Secretary of State has to consult a committee on all applications to release and market GMOs; this committee is the independent, expert Advisory Committee on Releases into the Environment (ACRE). ACRE has been chaired since its inception by Professor John Beringer of Bristol University and its members cover a wide range of expertise from ecology through molecular biology and genetics to human and veterinary medicine (details of current membership at Appendix 3).

22. In accordance with the requirements of the Act, public registers of information about applications for consents to release and market GMOs have been set up, and applicants have to advertise intended releases in local newspapers with sufficient notice to allow members of the public to comment, either to the applicant or to the Department of the Environment, Transport and the Regions. The registers, held at Environment Agency offices and now placed on the World Wide Web, contain details of each application and the full environmental risk assessment less any commercially confidential information, the advice given by ACRE, the final decision, and in the case of a research release, the report of the release. The full application is also available, less any commercially confidential material, from DETR.

23. Under the Directive, a Member State has to appoint one or more competent authorities which are responsible for the implementation of the measures. In the UK, there are three competent authorities for the Directive, the DETR, which has the lead, the Health and Safety Executive and the Department of the Environment (Northern Ireland).

(i) *Operation of Directive with regard to research releases*

24. In the UK there have been more than 150 releases since the Directive was fully transposed. While no consent application has been refused, ACRE has advised that additional risk management measures be imposed in some releases in order to ensure that the risks were minimised. No research release has yielded unexpected results. All applications have been decided within the statutory period, and most well within it.

25. In 1994, as a result of the experience gained, ACRE advised that research releases identified as being low risk, for which they established criteria, could be handled in a Fast Track Procedure. Under the procedure, an applicant must still provide the full information, but ACRE does not provide specific advice if the case satisfies the criteria. Decisions are reached within 30 days. This procedure has proved highly effective and useful: over the past three years, about 60 per cent of applications have qualified for the Fast Track Procedure. If officials have any doubts about whether the Fast Track criteria are fulfilled however, the case is referred to the committee.

26. The publicly available information is used fairly widely, particularly since it has been accessible on the Web. Comments are frequently sent to DETR following the advertisement of research releases and the register information. They are taken into account before a final decision is taken on any application.

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(ii) *Operation of Directive with regard to marketing*

27. Five of the 26 marketing notifications have been submitted directly to the UK competent authority; one of these is still under consideration. The average time to process the notifications in the UK was four months, the extension beyond the 90 days laid down in the Directive representing the additional time when the clock was stopped in order that the applicant could supply further information to the competent authorities. However, the time until the final decision was made at Community level varied between 14 and 21 months. This demonstrates that while the UK review of marketing applications has been carried out within a short period of time, there have been prolonged delays in the Community-level procedures and the operation of the Directive as regards marketing notifications is unsatisfactory.

28. There has been no commercial planting of genetically modified crops in the UK to date because before a plant variety can be added to the National List and freely marketed, clearance has to be obtained under Directive 90/220/EEC and, if appropriate, under the EC Novel Foods and Novel Food Ingredients Regulation. Such decisions are pending.

29. The remaining 21 marketing notifications were submitted to Germany (3), Finland (1), Denmark (1), France (7), the Netherlands (4), Belgium (2) and Spain (3). We do not have information about the efficacy of handling marketing applications in the other Member States before they are forwarded to the Commission.

30. The success of the operation of the Directive obviously should not be measured solely on the basis of the speed of processing applications. Rigorous review is necessary, in addition to a clear timetable. All marketing notifications are scrutinised by all the competent authorities.

3. THE MOST APPROPRIATE JURISDICTIONS (INCLUDING REGULATION AND HARMONISATION) FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

31. Since trial releases of GMOs are carried out in defined locations, it is appropriate that decisions about such releases are taken at national level, with some form of information exchange with other Member States. The marketing of GMO products however, presents a different scenario in which an approved product can be used anywhere in the EC. It is therefore appropriate in this case that decisions are taken collectively by the competent authorities using a procedure which allows each competent authority to review and reach a judgment on a marketing application in the light of its particular environment. Any procedure which removed this possibility would not give due attention to the property that organisms, unlike chemicals, are likely to behave differently in different environments. For these reasons, the current regime is appropriate, but the proposal in the Commission's draft amending directive to refer particular cases to the scientific committee needs to be examined carefully and in the light of the membership and expertise of that committee.

32. The need for national controls is mirrored at the international level in the Convention on Biological Diversity which was adopted at Rio in 1992. Article 8(g) of the Convention requires each Party to establish means to control, manage or regulate the use and release of living modified organisms, thereby reflecting the importance of taking into account the behaviour of any organism in a particular environment. The Convention does not specify further how Parties might achieve this goal, but UNEP's International Technical Guidelines for Safety in Biotechnology can play a major contributing role. These guidelines were first developed by the UK and the Netherlands in response to a call in Agenda 21 for international harmonisation in biotechnology safety. The guidelines were adopted at a global consultation in Cairo in 1995. A pilot project proposed by UNEP and funded by the Global Environment Facility has just commenced and will facilitate the introduction of controls in 18 countries.

33. However, GMOs are not only developed and used in a single country. Products are now starting to be traded on the world market, and to be moved between countries. A means for controlling such movements was initiated in 1995 by the Conference of the Parties to the Convention on Biological Diversity when the Parties decided to develop a biosafety protocol, specifically focusing on the transboundary movement of living modified organisms. Control is advisable for two main reasons: first, it will allow Parties importing such organisms to obtain, and be able to act on, information; and second, like the UNEP Guidelines, it will help to ensure that non-tariff trade barriers do not arise. The Protocol will establish a regime of advance informed agreement for the transboundary movement of living modified organisms (LMOs) that are likely to be defined to be similar to, or identical with, GMOs.

34. The Protocol is being developed by an Open Ended Ad Hoc Working Group established by the Parties to the Convention. The current draft contains a number of options regarding the scope of the organisms and activities to be covered by the protocol, the scope of application of the advance informed agreement and other procedures, and the possible inclusion of provisions on socio-economic impacts, and liability and compensation. The EU has proposed a broad scope, with exemptions, a range of possible procedures to be invoked by a Party of import as it considers appropriate, simplified procedures and multilateral agreements. The protocol will cover at least some LMOs used in agriculture.

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[Continued

35. The protocol is due to be finalised and adopted in February 1999. Only Parties to the Convention will be able to become Parties to the Protocol. Currently 171 countries and the European Community have ratified the Convention. The international level of jurisdiction which will be provided by the Protocol is appropriate for the transboundary movement of living modified organisms.

4. THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION

36. The Environmental Protection Act 1990 places the responsibility for decisions on the safety of the release and marketing of GMOs on the relevant Secretary of State. There is no consideration of impacts on competition.

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APPENDIX 1

Plant	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherlands	Portugal	Spain	Sweden	UK	Total
African Violet										1					1
Alfalfa		1										1			2
Barley				2										1	3
Beet		9	23	4	47	20		4	16	15		13	6	30	188
Broccoli		1												2	1
Canola															2
Cantaloupe												1			1
Carnation										3					3
Carrot										2					2
Cauliflower		5													5
Chicory		12			4				16	6				4	42
Chrysanthemum										1					1
Corn		7			2		2		1			6			18
Cotton							5					4			9
Eggplant									5						5
Eucalyptus												1		1	2
European Aspen					1	1									2
European Plum												1			1
Geranium									1						1
Grape					6										6
Kiwi									3						3
Lettuce					5										5
Maize	1	14			126	18	3		75	13	2	31		6	289
Marigold									15						15
Melon					3							4			7
Norway Spruce				2											2
Oilseed Rape		38	2	2	71	14				8		3	14	71	223
Olive									2						2
Paradise Apple														1	1
Petunia						2									2
Poplar					4									2	6
Potato	2	1	7	2	6	21			6	36	3	3	14	25	126
Rapeseed					21	14								4	39
Rice									1						1
Rose Gum														1	1
Scots Pine				2											2
Silver Birch				2											2
Soybean					4				3			3			10
Spring Turnip Rape													1		1
Spring Wheat		1												5	6
Squash					1				3			2			6
Strawberry									2					1	3
Sunflower					4					2		3			9
Sweet Cherry									3						3
Sweet Orange												1			1
Tasmanian Blue Gum											1				1
Thale Cress													1		1
Tobacco					34	1			1			5		6	47
Tomato					5		1		42	2	2	15		1	68
Wheat		1										2		1	4
Total	3	90	32	16	343	91	12	4	196	90	8	103	36	162	1,186

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[Continued

APPENDIX 2

Directive 90/220/EEC: Summary of marketing notifications

Date submitted	Competent authority to which notification was submitted	Description of GMO	Scope of application	Date of consent
22 June 1992	Germany	Pseudorabies virus strain	Immunisation of pigs against Aujeszky's disease	18 December 1992
29 March 1993	Belgium	Rabies vaccine	Live vaccine intended for bait for fox consumption	20 June 1993
11 October 1993	Germany	Pseudorabies virus strain	Immunisation of pigs against Aujeszky's disease	20 April 1993
23 November 1993	France	Tobacco modified for resistance to oxynil herbicides	Use in agriculture and tobacco industry	Commission adopted decision 8 June 1994
7 February 1994	UK	Oilseed rape hybrid system with herbicide tolerance	Seed production only	28 February 1996
6 December 1994	UK	Soybeans modified for tolerance to glyphosate herbicides	Importation, storage and use for animal feeds and food. Not for cultivation	7 May 1996
31 March 1995	France	Maize modified for insect resistance and herbicide tolerance	Use in agriculture in EC and importation of grain into the EC	5 February 1997
27 April 1995	Netherlands	Red Hearted Chicory modified for altered fertility	Seed production only	5 August 1996
27 July 1995	France	Oilseed rape hybrid system with herbicide tolerance	Importation of seeds for extraction of oil, and agricultural use in EC	Qualified majority vote in favour (5 December 1996). Consent not yet issued
6 March 1996	UK	Oilseed rape modified for tolerance to glufosinate ammonium herbicides	Importation of grain for food, animal feed and industrial uses	Consent to be issued shortly
12 March 1996	France	Maize modified for insect resistance and herbicide tolerance	Growing, import, storage and processing of grain and maize products for use in food, feed and industrial products	Vote not yet taken in Regulatory Committee
31 May 1996	France	Maize modified for tolerance to glufosinate ammonium herbicide	Agricultural use leading to animal and human consumption	Decision in favour made 18 March 1998. Consent not yet issued
3 June 1996	UK	Maize modified for insect resistance and herbicide tolerance	Importation of grain only	Consent to be granted shortly
12 June 1996	France	Maize modified for insect resistance	Production of maize in the EC and import, storage and processing for use in feed, food and industrial products	Commission adopted decision 22 April 1998. Consent not yet issued
5 July 1996	Finland	<i>Streptococcus thermophilus</i> modified as a test kit for the detection of antibiotic residues in milk	Use of the kit in dairy industry	21 August 1997
15 July 1996	Germany	Oilseed rape modified for tolerance to glufosinate ammonium herbicide	Same purposes as conventionally bred varieties in EC	Vote not yet taken by Commission
5 August 1996	Netherlands	Potatoes modified for altered starch production	Growing multiplication of breeding material, and processing starch for human consumption	Vote not yet taken by Commission
20 September 1996	Netherlands	Red Hearted Chicory modified for altered sterility and tolerance to glufosinate ammonium herbicide	Production of vegetable chicory crops	Vote not yet taken by Commission
25 September 1996	Netherlands	Carnation with modified flower colour	Cut flowers for purchase by consumers	1 December 1997
29 January 1997	Belgium	Oilseed rape hybrid system modified for herbicide tolerance	Growing and multiplication for breeding material, feed, food, and industrial uses	Vote not yet taken by Commission
24 October 1997	Denmark	Fodder beet modified for tolerance to glyphosate herbicides	Production of fodder beet in EC	Vote not yet taken by Commission
15 December 1997	UK	Maize modified for tolerance to glyphosate herbicides	Importation for processing for use as animal feed and food ingredients. Not be used for cultivation	Application not yet forwarded to the Commission
17 December 1997	Spain	Cotton modified for tolerance to glyphosate herbicides	Same purposes as non-GM commercial cotton varieties	Vote not yet taken by Commission
17 December 1997	Spain	Tomatoes modified for delayed ripening	Manufacture into food products	Vote not yet taken by Commission
17 December	Spain	Cotton modified for insect resistance	Same purposes as non-GM commercial cotton varieties	Vote not yet taken by Commission

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[Continued

APPENDIX 3

Current ACRE members and expertise

Name	Organisations	Expertise
<i>Chairman</i>		
Prof John Beringer ¹	Bristol University	Soil microbiology
<i>Deputy Chairman</i>		
Prof David Onions ¹	Glasgow University	Veterinary pathology
<i>Members</i>		
Dr Phil Dale	John Innes Centre, Norwich	Plant molecular biology
Dr Ian Garner ¹	Therapeutics, Roslin, Edinburgh	Animal molecular biology
Prof Alan Gray ¹	Institute of Terrestrial Ecology, Furzebrook, Dorset	Ecology
Ms Julie Hill ¹	Green Alliance, London	Environmental affairs
Dr Julian Kinderlerer ¹	Sheffield University	Molecular biology
Mr John MacLeod ¹	National Institute of Agricultural Botany	Botany, plant breeding
Prof Bev Moseley ¹	Formerly at the Food Research Institute, Reading	Food safety
Prof Nigel Poole ¹	Zeneca Seeds, Bracknell	Plant breeding
Dr David Robinson ¹	Scottish Crop Research Institute, Invergowrie, Dundee	Plant virology
Dr Kate Venables ¹	Royal Brompton Hospital, London	Toxicology, allergenicity
Dr Ingrid Williams ¹	Rothamsted Experimental Station, Harpenden	Agricultural entomology

¹ Various Government Departments have assessors on the committee. They include representatives from the Health and Safety Executive (HSE), Ministry of Agriculture, Fisheries and Food (MAFF), Scottish Office (SO), Welsh Office (WO), Department of Environment—Northern Ireland (DoE—NI), Department of Health (DH), Department of Trade and Industry (DTI), Office of Science and Technology (OST), and Forestry Commission (FC).

Examination of witnesses

DR JON BELL, Head of Additives and Novel Foods Division and MR NICK TOMLINSON, Head of Novel Foods Branch, Ministry of Agriculture, Fisheries and Food (MAFF), called in and examined.

DR LINDA SMITH, Head of Biotechnology Unit, and DR BILL PARISH, Senior Scientist in Biotechnology Controls Branch, Department of the Environment, Transport and the Regions (DETR), called in and examined.

Chairman

435. Thank you for coming to give evidence and assisting in our enquiry into genetic modification. Both of your departments some months ago provided useful background information in writing and orally on this subject. First, perhaps you would describe briefly your areas of responsibility.

(Dr Bell) I am Jon Bell, head of the Novel Foods Division in MAFF. My division is responsible for developing and implementing policy on genetically-modified foods and also has a co-ordination role in MAFF for biotechnology issues generally. On my left is Mr Nick Tomlinson who heads the branch within my division that deals with these issues. On my far right is Dr Linda Smith, Head of the Biotechnology Unit at DETR, who deals with the issue of the deliberate release of GMOs. On my immediate right is Dr Parish, one of the senior scientists working in Dr Smith's unit.

Lord Gallacher

436. Dr Bell, to what parts of the Commission's proposed revision of 90/220/EEC are you opposed and why?

(Dr Bell) Perhaps Dr Smith from the DETR can lead on this matter.

(Dr Smith) DETR officials are carrying out substantive negotiations on the directive. The United Kingdom has welcomed the proposal from the European Commission to amend the directive on deliberate release. The aim is to secure that the directive retains fully the requirement to protect human health and the environment and at the same time makes provision to allow the technology to develop and take due account of relevant experience. Many of the proposed changes broadly fulfil this aim. Although the details are still to be worked out in some areas and some amendments are needed to secure harmonised implementation across the Community, broadly we are happy with the thrust of the directive.

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[Continued]

[Lord Gallacher Contd]

However, there are some concerns. One of them is the proposal to remove from the scope of the directive products under development which would be covered by Community legislation to provide for specific environmental risk assessment similar to that in the directive. The Government are concerned that this could have the result of environmental effects not being taken adequately into account at the research stage because of the need to weigh them against other considerations addressed under product legislation. This would take the oversight of research releases away from the competent authorities for the purposes of this directive. These competent authorities have the relevant expertise and ability to evaluate these environmental risk assessments. This would not encourage public confidence in the regulatory regime and, further, the proposal would not be helpful for those wishing to conduct research releases because one research release might require several approvals if this particular procedure was adopted. This could result in far more bureaucracy and longer time than the current maximum of 90 days before research approval was granted.

Another concern is the loss in the proposal of the possibility for Member States' competent authorities to request simplified procedures. Under the existing directive only one simplified procedure has been adopted, but this has proved very important. While it does not reduce the information and risk assessment requirements it allows a single application to cover an entire plant breeding programme. The Government consider that the simplified procedure should be retained along with the facility to introduce other simplified procedures in order that the procedures can be adjusted if appropriate to reflect growing experience.

Chairman

437. Are those the only criticisms at the moment?

(*Dr Smith*) There are further points. Do you wish me to stop here or go on?

438. I think, perhaps, I would rather like you to continue.

(*Dr Smith*) There are two further concerns. The Commission proposes to introduce two categories of research releases. At first sight this may be thought to be equivalent to the United Kingdom's fast track procedure for approvals for research releases by which for certain releases our own advisory committee on releases to the environment has identified certain things as low risk. We are able to make decisions on applications within 30 days, although without any reduction in the information and risk assessment requirements. That has worked satisfactorily in the United Kingdom. However, the approach proposed by the Commission for the two categories is different and may be difficult to implement because the categories are only broadly defined at present. As a consequence, we are concerned that this may result in uneven implementation across the Community. In addition, the procedures for the categories for which there is considered to be sufficient experience do not lighten

the burden in terms of information requirements but only reduce the time within which the authorities have to make a decision. Therefore, this does not fully reflect the risk-based approach and in future when the number of applications increases could perhaps compromise the ability of the competent authorities to give due consideration to less familiar releases.

The other concern is that the Commission recently decided to seek the advice of the relevant Community level scientific committee on all notifications to market GMOs and the proposal for amendment of the directive would hamper this procedure. The Government wish to ensure that any decisions made on the renewal or otherwise of consents are based on sound science and referral of certain notifications to a scientific committee may help to secure this. However, the current proposal does not set out any period within which the committee would have to assess each application; nor does it set out the role of the committee in the approval process. We want that to be clarified.

439. Do you think that this may result in the whole process taking longer in future than it does currently?

(*Dr Smith*) That is one of the concerns. Although the new proposal and directive sets a clear timetable for all the other steps in the procedure there is no timetable set for that which could introduce lengthy delays.

440. What about the attempt to introduce agreed principles for risk assessment? Do you think that would be effective? Are you in favour of that?

(*Dr Smith*) We are very definitely in favour of that. One of the problems with the existing directive is that Member States have adopted different views on the risk assessment procedure. Although there has been a competent authority working party looking at that matter, it would be much clearer if it was set out in the directive so that Member States could work in harmony.

441. Are you happy with the introduction of an ethics committee?

(*Dr Smith*) In the recitals to the directive there is a proposal for an ethics committee to look broadly at biotechnology issues. We believe that that is a good idea.

442. Referring to the scientific committees at Community level, are you happy with the method by which their membership is determined?

(*Dr Smith*) We have some concerns there. It is not completely transparent how the members of those committees are selected. We have been trying to find out more information about that.

443. Are you happy with the seven-year limitation on consents for commercial releases?

(*Dr Smith*) We have some concerns about that for two reasons. We do not have a problem with the idea of having a time limit on the consent provided there is a well set out procedure for reviewing the consent if things are satisfactory and provided the consent continues in force until that has been resolved. There is also a concern as to whether seven years is the

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[Continued]

[Chairman Contd]

appropriate length of time. We would like to discuss that during negotiations on the directive.

444. Do you believe that such a period should be longer or shorter?

(Dr Smith) We have had representations both ways. Plant breeders who have obtained marketing consent for a particular genetically-modified crop need to breed that trait into different varieties and perhaps seven years will not give them long enough in order to bring those different varieties to market and make use of them.

445. There are provisions for monitoring in the revised directive, but it does not say much about the nature of the monitoring. Do you think that that should be more specific?

(Dr Smith) Yes. The Government are committed to ensuring appropriate monitoring for the introduction of genetically-modified organisms into commercial agriculture. The existing situation is that consents for experimental releases for marketing are given on the basis of a risk assessment which has to demonstrate that any risks to human health or the environment have been avoided or minimised. The purpose of monitoring consents, particularly after they have been granted, is to verify that the assumptions in the risk assessment are correct. We feel that for the post-marketing consents it should be specifically identified on a case-by-case basis what the monitoring should be. It should be based on the risk assessment for which the consent is granted.

Lord Wade of Chorlton

446. Are you aware of the response to these proposals by other Member States?

(Dr Smith) The negotiations on the directive started in the Council working group last week. There is a working group meeting this morning at which countries will be stating their position. Generally, there is very favourable opinion among other Member States for the amendments to the directive, although most countries have reservations about certain aspects and wish some of the proposals to be clarified before they can agree with them.

Lord Willoughby de Broke

447. You said that you were in favour of retaining the simplified procedures for research releases but that they may be excluded under the new proposals. What sort of support have you had for the simplified procedures route among fellow members of the European Union?

(Dr Smith) The current simplified procedure was an amalgamated proposal by several countries. France, Germany, the United Kingdom and the Netherlands had proposed simplified procedures. The one adopted was an amalgam of those proposals. We have support among other Member States for that.

Lord Wade of Chorlton

448. It has been put to us that risk assessment using evidence gleaned from tiny trial releases designed for safety is a farcical process. Do you agree

with that? Is there a better way of dealing with risk assessment?

(Dr Parish) In the Government's view there are no valid alternatives to research trials carried out in the field to generate the necessary data for either scaling up research trials in the environment or making applications to place a product on the market. It is important to start with the laboratory studies to obtain basic information, for example to determine whether the product may be toxic or allergenic. But that data only helps to establish whether or not the product is hazardous. It is very important to validate those laboratory studies in a real field situation and find out whether those hazards are likely to be realised and what the magnitude of the consequences may be. Therefore, that establishes the particular risk in the field. The current deliberate release directive sets out some important principles in the 10th, 11th and 12th recitals with respect to the carrying out of field trials to generate valid data to place products on the market. They also set out the step-by-step principle whereby one starts releasing genetically-modified organisms in very small trials with risk management in place. For example, for oilseed rape one may consider using isolation distances or pollen barriers. As one generates more data from those field trials one makes an application to scale up the size of the release. We are very much in favour of the step-by-step principle in order to generate data to satisfy ourselves that it is safe to scale up and once data is available from larger releases we have data to support an application to place the product on the market.

449. In your view how do the present risk assessments take into account the potential secondary effects of GM products?

(Dr Parish) It depends on how one chooses to define the term "secondary effects". The first interpretation is whether the genetically-modified organism has a direct effect. For example, an insect-resistant crop may affect the target pest. If we mean "secondary effect" to mean the effect on those organisms that may eat or parasitise those pests then those secondary effects are currently considered in our risk assessment. If we mean "secondary effects" as meaning effects that are not exerted by the GMO itself but as a result of managing the GMO, for example changes in herbicide use or other measures that may be necessary to grow the product in an agricultural situation, those effects are not formally addressed in our current risk assessment under the GMO regulations. However, it is important to bear in mind that the use of herbicides on such crops would be governed under other relevant legislation, for example the pesticides regulations, which also scrutinises safety to the environment and human health before making a decision on whether or not to give approval. We are currently taking steps to address the wider issues in respect of management to review our current legislation and identify whether or not there are any gaps.

450. When you talk about the assessment of risk are you looking for a nil risk or levels of risk which

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[Continued]

[Lord Wade of Chorlton *Contd*]

you regard as acceptable? When does a risk become acceptable?

(*Dr Parish*) That is a very searching question. First, it would be very unscientific. ACRE would not be able to come to a judgment on the concept of zero risk. There is no such thing as zero risk. One must accept that the growing of crops in agricultural situations will have some side effects on wild life, just as the result of cultivating a crop and controlling necessarily weeds and pests. Therefore, one must look at risk in terms of ensuring that it is minimised and address it on a case-by-case basis for each application that is looked at.

Lord Jopling

451. There is considerable concern about the adequacy of the steps being taken in relation to risk assessment. The Sub-Committee has been provided with a paper by Prof Williamson of the University of York entitled *Biological Invasions* first published in 1996. This paper is concerned with modified corn. He points out: "In corn, male sterility is a most useful agronomic trait. . . Texas cytoplasm varieties are male sterile because of a change in a mitochondrial gene. . . Remarkably, the same molecular mechanism that made the plants male-sterile also made the plants susceptible to a fungal pathogen, *Bipolaris maydis* race T. About two decades after the gene, T-urf13, came into commercial use the fungal disease devastated the corn containing that gene, which was by that time 85 per cent of the US corn hectareage, and made the innovation useless. The molecular details were known, the pathogen was known, but the interaction was not predicted and the consequences did not appear until the new genotype was in full commercial use." That is two decades later. It seems to me that in a situation of this sort in another case the problem may not be a fungal infection of that species but perhaps a secondary effect on human beings who eat that product. Are you not concerned by evidence of this sort? How can you carry out proper risk assessment that can cover an eventuality of that kind? That is what causes many of us on this Sub-Committee anxiety.

(*Dr Smith*) In assessing any proposal whether or not to release a genetically-modified organism the regulations require a large body of evidence to be provided. We offer a step-by-step approval procedure such that these trials are started in a small way and further information is gathered before the product is approved for marketing. Before the product is approved for marketing it is scrutinised by the competent authorities in all the Member States. They will make their decision based on the evidence before them, but there is always a possibility that unpredicted effects may arise. That is one of the reasons why monitoring of the product once it has been approved is so important. That is why we welcome the initiative of the Commission to take that into account. One of the conditions of any consent that is granted is that the holders of the consent must keep up to date with developments and inform the competent authorities as soon as new information is available about the particular product such that the consent can be

reassessed. If appropriate, consent can be withdrawn by the authorities. But uncertainty and unpredicted effects are such that we have to make the decision on the best available evidence. The monitoring and procedures in place for checking what happens when products are introduced on to the market are part of the consent procedure.

(*Dr Bell*) I very much endorse that general approach. At the moment, we are using the best advice that we can obtain in this country when considering these applications. That is supplemented and amplified by the best advice that other Member States can offer. This is not a decision that we take in isolation. It also builds on experience that has been obtained elsewhere, including in the United States where this technology is well advanced. But we cannot give a one hundred per cent guarantee that every eventuality has been covered. It is only possible to do that in the context of the knowledge of those who are involved in it. Clearly, it would be difficult to see how we could ever reach that position. We shall learn from experience, and experience in other areas indicates that products should be approved and allowed to go into the food supply, provided they are considered safe on the basis of current knowledge. Therefore, monitoring is a very important back-up and reassurance for picking up any longer-term effects. We are considering now how best that can be done.

452. To sum up what has just been said, is it right to say that we are embarking into a potentially dangerous unknown area?

(*Dr Bell*) I think that that is overstating the case. Clearly, if the Government and their advisers thought that they were taking inordinate risks in the way that these things were being put through the system they would not be approved until further evidence was available. This is a matter involving public health and the Government take it very seriously as you would expect. It will not agree to sign off a request for approval for something to go on the market here or in the European Union that may carry serious health risks. Every piece of scrutiny that can possibly be carried out is carried out. This draws on knowledge worldwide, not just in this country.

453. Dr Smith, is it a potentially dangerous unknown?

(*Dr Smith*) I endorse what Dr Bell has said. We have a good understanding of plants and their biology. The advice that we have received from our expert committee on risks to the environment based in this country is that it would not grant a consent unless it was satisfied that the risks had been minimised and it had sufficient information available to it before making that decision. If it feels that it does not have sufficient information on a matter where it has identified a potential risk it will ask the applicant to obtain that information before approval is granted.

Lord Moran

454. Lord Jopling quoted the American case. I understand that it is impossible to predict everything. But in that particular case after 20 years 85 per cent of

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[Continued]

[Lord Moran *Contd*]

the US crop was of the single variety that caused a disaster. Do you think that there should be some arrangement to make the introduction of new species, once consent has been agreed, more gradual, through monitoring, and prevent a wholesale catastrophe of that sort from happening?

(*Dr Smith*) I am not familiar with the paper that has been quoted. I am not sure if the observed effect was as a result of a genetically-modified crop or conventional breeding.

Lord Jopling

455. Professor Williamson claims it is genetically modified: *Zea mays*.

(*Mr Tomlinson*) Given the timescale referred to in the paper and the fact that it was being grown commercially 20 years ago, it is extremely unlikely that it is a genetically-modified variety in the sense referred to in directive 90/220. It may well be that a gene from another variety of maize had been incorporated through conventional plant breeding. That points to the fact that there is a need to ensure there is a constant turnover of plant varieties to minimise the build up of plant diseases.

Chairman

456. This is a matter that can be taken up with Prof Williamson when he comes before the Sub-Committee next week.

(*Dr Smith*) As none of us is immediately familiar with the specific papers, perhaps we can submit a supplementary comment after this session.

457. I should like to return to one matter to which Dr Parish referred, namely the indirect environmental and other effects which are not currently taken care of by existing committees. Dr Parish said that the department was looking at the legislative implications of taking account of that. Can you say a little more about Government thinking in that area? We have had various recommendations put to us either for changing the existing remit of the environmental committee or introducing some other overarching committee. How can account be taken of such factors in the regulatory process?

(*Dr Parish*) The Government's thinking on addressing the indirect effects is still very much in its early stages. We have been discussing with English Nature and other bodies such as the Royal Society for the Protection of Birds concerns about biodiversity and the possible effect of GMOs on species if they were introduced on a wide commercial scale. Once we have finished our discussions with them we shall be putting proposals or options to Ministers later this summer. That will go out for wider consultation in the autumn. The options that have been raised, for example expanding the remit of ACRE or having another regulatory committee to look at overarching issues, will be considered and put to Ministers. We are still very much in the early stages.

458. You mentioned English Nature. You will be aware that that body has called for a moratorium for a

number of years until further research has been carried out and we know more about the problems. This is not a wild and woolly bunch; it is the Government's own organisation that has responsibility for advice on nature conservation in England. Do you have a view on that?

(*Dr Smith*) English Nature has submitted a paper to this Sub-Committee. As statutory advisers to the Department of the Environment that statement is being taken most seriously. It is one of the inputs into the review of the way in which risks are assessed which the Government are undertaking at the moment.

Chairman

459. Therefore, you do not rule out the possibility of a moratorium?

(*Dr Smith*) The evidence that has been submitted is being considered. I should make it clear that the call by English Nature for a moratorium is very specific. It refers to the possibility of one particular genetically-modified crop being introduced into commercial agriculture: GM oilseed rape. At the present it is still awaiting marketing approval by the French competent authorities and those responsible for putting the seed on the national list of seed varieties in the United Kingdom or the common catalogue in the European Union. At present this product does not have approval.

460. On previous occasions when there have been calls for a moratorium you have always argued that you do not have freedom to act in that way under European and World Trade legislation. Is there any significance in the fact that you have not made that point this morning?

(*Dr Smith*) Any genetically-modified product which has approval under the European Union system must be available in the market in all Member States. In order to take action under Article 16 to prevent it going on the market in an individual Member State the particular Member State must have additional evidence that there are consequential effects which was not available at the time approval was granted. The Member State can then take action to ban the product. It must then submit the evidence to the European Commission in order for that to be justified and considered by other Member States. Under our own Environmental Protection Act any product that has approval from the European Community under Directive 92/20 is excluded from the controls under the Act.

461. Is English Nature arguing that new evidence has come to light and therefore the United Kingdom is entitled to act in that way?

(*Dr Smith*) That is one of the points that we shall look at in studying the evidence that English Nature has put forward.

Lord Willoughby de Broke

462. Reference has already been made to monitoring. Monitoring criteria need to be explicit. What would you monitor for? Who would conduct the

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monitoring? Are you satisfied that post-release monitoring carried out by the commercial companies which produce GMOs is putting the responsibility in the right place? We have heard from several witnesses that they have concerns about this.

(*Dr Smith*) As I said in response to an earlier question, the Government consider that the monitoring should be based on the risk assessment that was made before consent was granted. The purpose of the monitoring is to verify that the assumptions in the risk assessment is correct. Therefore, the assessment that is made forecasts what will happen on release into the environment or marketing of the GMO. It is reliant on information on both the organism itself and the environment into which it will be released. The risk assessment identifies the characteristics which play a role in determining risk. Appropriate monitoring before, during and after release will ascertain whether the predictions are correct and, if not, what measures can be taken. That is why the Government place such emphasis on the step-by-step development of GMOs which builds up knowledge. If the risk assessment identifies the transfer of genes to weedy relatives as one risk that can be monitored post-release to see whether or not that transfer has taken place. For example, if the risk of volunteers has been identified that can be monitored post-release. This kind of monitoring will parallel the monitoring of medicines after they go on the market.

You asked who should do the monitoring. The Government are clear that it is the consent-holder who should do it. Monitoring is already a condition of all experimental releases that are approved in the United Kingdom both during trials and after them. The consent-holder is required to report back to the Government the results of that monitoring.

As to monitoring for marketing consents, under the present directive conditions can be placed on marketing consent for monitoring. The particular regime will have to be decided on a case-by-case basis depending on the particular product to be approved. For example, a marketing consent-holder may need to conduct monitoring of the product as it is released into commercial agriculture; he may need to have an arrangement with the farmers growing the crop in order to report back what has happened. You asked who would do the monitoring. Companies may wish to employ independent bodies to carry out the monitoring; or there may be a requirement that the consent-holder should conduct its own long-term trials post-marketing consent in different ecosystems in parallel with commercial release to verify whether the risk assessment provided turns out to be correct in practice.

In terms of risks to the environment, the Government is in discussion with a number of farming industry bodies about a voluntary initiative that is being developed to regulate the introduction of genetically-modified crops into commercial agriculture. This initiative is called the Supply Chain Initiative on Modified Agricultural Crops and it includes a monitoring component in which farmers report observations to seed merchants or to this new body. Certain requirements will be introduced and

enforced and the results analysed. The outcomes will improve risk assessments and safety regimes in future. As to environmental concerns, the Government do not see a role in funding such work except perhaps in relation to food.

(*Dr Bell*) The Government are keen to explore fully the possibility of setting up some sort of monitoring system to pick up any public health issues that may come to light in the longer term as a result of the products going into the food supply. I emphasise that this is very much a back-up to the main scrutiny that goes on before anything is allowed into the food supply. They have asked the Advisory Committee on Novel Foods and Processes to look into this possibility. From preliminary examinations that it has been able to carry out, it appears that it may be possible to link databases of disease frequency now in existence, and which can be added to over time, with food consumption statistics to pick up any changes in the pattern of human disease and link them back to food consumption, if indeed that is the source. How that would work in practice, and who would do it, still needs to be looked at in more detail. But in this area we see perhaps a rather greater role for government than on the environmental side, simply because the information needed to determine food consumption patterns is very diffuse. It may well be that the Government need to have a co-ordinating role in drawing all of that together. So it may well be that there will be a greater role for the Government than perhaps in other areas as the process will have to involve the food supply chain and all aspects of it. It is still early days, and it is being actively looked at, but it appears as if it will be possible to set up some mechanism the details of which will have to be worked out.

Lord Jopling] Is it not wholly inappropriate to have the companies who introduce the GMOs carrying out the monitoring? Do you agree that the example of the tobacco companies who succeeded unbelievably over decades in shrouding the effect of tobacco on human health has been one of the disgraces of the age? Surely, it is better to have this crucial task carried out by an independent body financed by those companies who wish to introduce these organisms. Is it not best to pass legislation so that it does not cost the Government any money and so that the public know that the monitoring is carried out in a truly independent way?

Lord Moran

463. My Lord Chairman, before the witnesses reply, I agree entirely with what Lord Jopling has said. As I understand it, you suggest that monitoring should also be done by farmers. One wonders whether farmers are competent to do it. It may be that certain matters do not affect the farmer directly, such as effects on wildlife and so on. Should that not be done by scientists? Is that not another great defect in the proposals?

(*Dr Smith*) I am sorry if I gave the impression that the Government intended that farmers do the monitoring. That is not the intention. The requirement

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would be on the consent-holder to carry out the monitoring. In placing conditions on the consent it would be possible under the legislation to require the monitoring to be done by an independent body. The point I sought to make was that the experience of the farmer would be in addition to the statutory monitoring on a voluntary basis, but the consent-holder would be required to do the monitoring. Indeed, the consent-holder would need to employ appropriately competent scientists to carry out the task. If the monitoring was to see whether the trans-gene had translocated into wild relatives a scientific assessment would be required to verify that. Monitoring to see whether there were volunteers in subsequent crops might be something on which farmers could report as part of the arrangements. It is important that the monitoring requirements are dealt with on a case-by-case basis such that monitoring specific to a particular product is wholly appropriate to the potential risks of the particular product.

Lord Jopling

464. Can I have an answer to my question about the inappropriateness of having the companies carrying out the monitoring? Should it not be done by an independent public body financed by the companies?

(*Dr Smith*) That is not the arrangement at present. The present arrangement is that the companies are required to do any monitoring. We could make a requirement that it should be done by independent bodies. The Government are carrying out some of their own research on the introduction of genetically-modified crops. The Department of the Environment, Transport and the Regions has a research contract in place to monitor the introduction into the United Kingdom of any crops that are given marketing consent. But at present we do not have any arrangements for doing this work and recovering the cost from companies. Clearly, that is something that can be considered as a future requirement.

465. Why do you think that the companies are competent to do this, given the example of the tobacco companies?

(*Dr Smith*) Because the monitoring would be scrutinised by the competent authorities, unlike the situation with the tobacco companies the process would be a statutory one. It would impose conditions on the consent, such that the Government would need to be satisfied that the monitoring was being carried out appropriately and fulfilled the conditions imposed under the consent and scrutinised the results.

Lord Willoughby de Broke

466. Dr Smith, does that answer go far enough in addressing the concerns that we have heard expressed by consumer organisations and others who make the point just made by Lord Jopling? They no longer have faith in the ability or competence of companies who promote seeds, sprays or whatever to carry out the post-release monitoring procedures. Do you not think

that the department should be looking at it much more urgently in view of the big public debate now taking place on GMOs? It is reasonable to expect some sort of response to the widespread public concern on this matter particularly in regard to post-release monitoring.

(*Dr Smith*) I shall certainly take that message back to the department for consideration.

Chairman

467. Do you consider that the net environmental effect of GMOs may be beneficial? We have heard evidence from the United States about the tremendous savings in the use of herbicides and pesticides as a result of the growing of genetically-modified crops, although those claims are treated with considerable scepticism by witnesses and others in this country. On the other hand, here the concerns centre largely on the loss of biodiversity. Do you not consider that biodiversity is already being lost to the same or possibly a greater degree as a result of the current use of conventional herbicides and pesticides? Therefore, do you think that any assessment of the risks of genetically-modified crops should be made in the context of the risks from growing non-genetically-modified crops and their associated chemicals? If that is the case how do you think it may be done?

(*Dr Bell*) The Government are aware of reports from countries where GM crops have already been grown on a large scale, principally the US and Canada, that there may be significant environmental benefits from cultivation particularly in terms of reduced inputs with perhaps better targeted and environmentally-friendly herbicide use, for example those that break down very quickly after use. Although a lot of the claims are viewed with scepticism by some of the pressure groups and environmental organisations, it must be accepted that there are gains of this type; otherwise, it is hard to see why farmers should sign up in such numbers in those countries to plant such crops. As you would expect, they are most interested in the benefits to themselves commercially. Those benefits must accrue from some savings in inputs. The fact that we are told that up to one third less herbicides are used on some of these crops therefore appears to have some substance to it, although the figures may be debatable. It is also true that some of these crops provide higher yields than conventional ones, but evidence suggests that that is a fairly minor aspect (two or three per cent). If it is the case that the result of planting these crops means less inputs one can see some very definite environmental benefits flowing from them, given the widespread use of herbicides and pesticides in intensive agriculture. The Government are aware of that and feel that that factor should be taken into account by critics of these crops. The weight to be given to it is a matter for debate, but that some potential benefits arise from the use of these products cannot be ignored. On the down side, there has been considerable argument—which we have all seen in the press and elsewhere, and departments receive representations in writing and

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personally from those who remain concerned about it - about the pressure on biodiversity resulting from the widespread introduction of these crops. That needs to be taken very seriously. But it must be looked at in the context of farming at the present time and how it may develop in future. It is already a very intensive activity for the most part and involves quite large inputs. The view of the Government is that cropping areas are not considered to be the main reservoirs for wild life; they are already heavily treated with pesticides and herbicides. Usually, it is the aim of farmers to keep them as weed-free and pest-free as possible. That is the present situation. Field margins, hedgerows, wooded areas and other wild-life reservoirs of that type are considered to be far more important in terms of support. The Government wish to see that situation continue if these crops come into widespread use. The impact that they are likely to have on wild life needs to be viewed in that context. It is really a matter of replacing existing intensively-reared crops with other crops of this nature, not necessarily moving into less intensively farmed areas or affecting hedgerows, wooded areas or general wildlife reservoirs that now exist. That is one aspect of it. In terms of biodiversity, there is no reason to believe that the introduction of these crops will necessarily replace all other types of crops or that the position which prevails in the early years of having modified crops will necessarily be the position for all time. These crops will be developed and perhaps crossed with conventional crops very much in the way that has happened over many centuries by way of conventional breeding. We have moved from varieties hundreds of years ago to something totally different now. It is expected that genetic modification will be another tool to be used to move things on further. That does not mean that everything we have now will disappear; rather, that there may, in fact, be greater diversity. It may be diversity that does not occur through natural processes but diversity of a different sort that nevertheless brings benefits comparable to that that we have experienced through conventional plant breeding thus far. It needs to be viewed in the wider context, but the weight that is given to various aspects of the debate is something that must be considered. The Government are looking very closely at that. One must weigh up the pros and cons of all these matters in the wider context of the changes to the agricultural environment and how the Government wish to see agricultural development take place over the coming years, not so much in the field of safety which is being viewed specifically in its own right.

468. Why do you think that the environmental benefits of GM crops are accepted in the US even by environmental pressure groups but not here?

(*Dr Bell*) That is an extremely good question to which we would all like to have the answer. I do not think that we have a better answer to that than anybody else. It may reflect a difference in culture between people on each side of the Atlantic and the way they view new technology. One can speculate about these things; it is difficult to pin it down. It may be that it turns on the general debate about intensive agriculture

as a whole rather than perhaps this particular aspect of it. We have seen indications of that in a good deal of the arguments that have been put forward so far. They are arguments that can be applied to agricultural intensification generally and are not necessarily specific to these particular crops. Perhaps intensification of agriculture in other countries does not give rise to the same concerns as here. It is hard to pin it down. We are not really in a position to say that it is for one reason rather than another.

Lord Moran

469. Do you think there is a danger that if genetically-modified crops are introduced and are very successful it may lead to the production of monocultures with the disadvantages that that entails? We have the example of Round-up ready soya in the United States. From the point of view of the farmer it is immensely satisfactory and is grown very widely. If one has a single crop spreading through the country and anything goes wrong obviously it will be a very serious matter. Are you worried about that?

(*Dr Bell*) The Government would be surprised if that was the overall outcome of developments in this area. Undoubtedly, the first one into the market gains the biggest toehold. That is perhaps what one sees now with the particular crop developed by Monsanto. It would be extremely surprising - our knowledge of what is in the pipeline confirms this - if it was allowed to dominate the market in quite that way in the medium to long term. There are many other companies who are developing alternative products in this area. Obviously, they also wish to have a share of the market. What we see is that one has reached the market first, but others are coming along. It is very unlikely that we will end up with a monoculture. At the end of the day it may well be that this particular type of technology, which can move beneficial genes around in a freer and quicker way than can be done by conventional technology, will gain a fair hold in terms of the way that these crops are developed in future. Perhaps conventional breeding will therefore be of lesser importance over time. But generally the Government would be surprised if one particular trait, as in the soya bean, totally dominated the market and created the sort of monoculture environment to which you refer.

Lord Wade of Chorlton

470. It has been suggested to us that one of the reasons for the difference in attitude between the Americans and Europeans is confidence in the regulatory system. It is said that the American public see theirs as an open, clear and certain system in which they have great confidence. Do you have any comment on that?

(*Dr Bell*) That is an argument that is often heard. It may have some truth in it. One does not wish to deny it. In response, this Government are keen that we should take as many steps as possible to open up the regulatory system in this country in a variety of ways, certainly by making information more available, the

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work of the expert committees more transparent, holding open meetings wherever possible, publishing minutes and making annual reports available on the Internet. All of these kinds of things are happening now and will be taken further in due course. We are in the process of setting up the Foods Standards Agency as a way of focusing responsibility for the controls on food in one particular body. The intention is to make that an open body from the beginning, to make access very easy and to make full use of modern technology, such as the Internet, so that people can become involved in the process. There is a good deal either going on or in the pipeline to try to open up the process. Having said that, in the field of GMOs we can argue that in this country we have rather more detailed scrutiny arrangements in place than perhaps in the United States. It may well be that the American public have more confidence in their institutions. But in this area I would argue that we have a very thorough pre-marketing approval system which is more detailed than is operated in the States. If you like, there is a rather more liberal regime in the US. One can argue that such a system has advantages and disadvantages. But if anything I believe that our system should command greater public confidence in that respect. Whether or not it does is an open question, but we are very thorough about the way in which we scrutinise these crops and the products that come from them.

Chairman

471. To return to the differences between the effects of GM and non-GM crops where comparisons are not being made and perhaps should be, we know that there has been a good deal of fuss about the bacterium *Bt* being incorporated in maize and other crops. However, we understand that the *Bt* bacterium is widely used in organic farming. It is sprayed on crops as a pesticide and, as a consequence, it may have a more serious impact in relation to building up resistance than when it is incorporated in a genetically-modified crop. Do you believe that such factors should be taken into account?

(*Dr Bell*) That is certainly a possibility and must be taken into account. The use of that particular organism as a pesticide is regulated under the Control of Pesticides Regulations. Its use is subject to evaluation of safety and efficacy. Inevitably, the use of any of these things will lead to a build-up of some resistance. That is the nature of these substances. There are obviously downsides to the use of organisms like that as a natural pesticide in the same way that there are in the use of other kinds of pesticide. They are by no means free of drawbacks. For instance, they can attack organisms other than the pest; they are not necessarily specifically targeted. Making a comparison between conventional use and building it into a plant is perhaps a more difficult concept, but such a comparison could be made. I do not think it can be said that the benefits come out all one way or all the other. There are advantages and disadvantages in using those types of organisms to control pests, whatever the means of doing so.

(*Dr Parish*) I reinforce what Dr Bell has just said. The only difference in exposure to an organism is the way that the toxin is delivered to the target pest. When *Bacillus thuringiensis* is applied as a spray it can be argued that it is being delivered to the pest in a somewhat less targeted form than if it is in the plant tissues of the crop which will only target the pest that is chewing the material. Exposure to *Bacillus thuringiensis* if applied by spray will be episodic; it will be applied only at intervals when it is perceived to be a problem with the pest, whereas with *Bt* being incorporated in the tissues of a GM crop it will be there all the time and will affect only the organism that chews it. Therefore, the *Bacillus thuringiensis* that is applied by spray cannot be considered to be necessarily benign; it has the same potential to have non-targeted effects as if it is in the tissues of GM crops. There are still potential problems for eventual resistance arising from the overuse of *Bacillus thuringiensis*.

Lord Moran

472. I wonder whether the environmental risks associated with the continuing use of genetically-engineered animals and fish had been taken sufficiently seriously. What regulations are in place to ensure that a comprehensive assessment of the risk of escape from containment and the impact of that escape has been undertaken and the risk minimised? How is this likely to change when the regulations under a modified Directive 90/219, which applies only to micro-organisms, are prepared? We have had helpful written evidence from the Scottish Office on an experiment to breed transgenic salmon. Although they were bred on the banks of a loch they were contained. We understand that the Health and Safety Executive made numerous visits to ensure that the containment was satisfactory. Initially, it was not but it was subsequently improved. The experiment had come to Scotland from North America. I believe that it has been discontinued for it was not very successful. But it had the potential to put these transgenic salmon into a loch that contained wild salmon, with all the very serious consequences that might have flowed from it.

(*Dr Smith*) You are right that Directive 90/219 applies only to genetically-modified micro-organisms. However, the Health and Safety Executive's regulations predate the directive by a number of years and have always applied to all genetically-modified organisms in containment as far as human health is concerned. When the regulations were made to implement the directive they were intended to cover genetically-modified micro-organisms because there was power under the directive to make such regulations. But the Government have taken very seriously indeed the possible escape of larger organisms. In addition to the control of GMOs in containment, which provides protection for human health, the Government have extended the legislation to protect the environment from genetically-modified animals and plants in containment. To explain how it works, it is an offence under the Environmental

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Protection Act 1990 to release any genetically-modified organism into the environment or allow it to escape without prior consent from the Secretary of State. By regulations made under the Act anyone keeping genetically-modified animals must carry out an assessment of the risks to the environment. That assessment must include the risks arising from the escape of such animals. That risk assessment enables the keeper of the animals to put in place suitable containment measures to minimise damage to the environment resulting from such an escape. Under delegated powers from the Secretary of State the Health and Safety Executive's inspectors inspect the appropriateness of the controls when visiting premises normally for HSE purposes. If having considered the risk assessment carried out by the person keeping animals the inspectors feel that the controls are unsatisfactory and escape is possible the keeper will be told to improve his containment facility to prevent escape or be required to apply for a consent under the deliberate release legislation. Therefore, it is an offence to allow the animals to escape and people must take appropriate precautions to prevent that. When Directive 90/219 as amended is brought into United Kingdom law it will still apply only to micro-organisms but during its implementation the Health and Safety Executive and the department will frame legislation so that it continues to provide for human and environmental protection but has additional provisions for notification by anyone intending to keep genetically-modified animals and plants, such that we will be able to be better informed as to which premises are doing this.

The Government have been concerned about the possible escape of genetically-modified fish into the environment. We are considering the Otter Ferry salmon which were being kept on land in containment. Health and Safety Executive inspectors on behalf of the Secretary of State for Scotland visited the premises many times to ensure that the containment facilities there would prevent the escape of those fish into the wild. If there were a proposal—I stress that there has not been so far—for anyone to keep genetically-modified fish in, say, a cage in a loch in Scotland in the way that farmed salmon are kept the Government would view it as a deliberate release and approval would be needed by the Secretary of State before the fish could be allowed to be kept in cages. We would assume that they could escape from the cages and it would be a deliberate release. We do not know whether or not such a release consent would be granted, but certainly no one would be allowed to put genetically-modified fish into a loch until the case had been considered by the Secretary of State and consent had been granted.

Chairman

473. Presumably, that would have to go through the EC procedures?

(*Dr Smith*) If it was for experimental purposes it would be just judged in the United Kingdom and our own advisory committee could consider it. If the fish had obtained marketing consent that would have gone

through the European procedures. We have published some guidance on this matter.

(*Dr Parish*) The Government have been considering genetically-modified fish for some time. Much work has been carried out in laboratories. Work is taking place in countries like China, Japan and Norway. It is viewed by the Government with a considerable degree of concern, especially in the case of species like salmon that can cross-breed with native populations. Problems have been observed in Norway with farmed salmon breeding with native salmon in different fjords and the genes integrating into different native populations. We published guidance in 1996 on genetically-modified fish. That sets out very clearly the principles of risk assessment and the way that we believe fish should be regulated. It makes very clear that anyone intending to farm fish in a sea cage must apply for deliberate release consent if he wishes to carry out that work. You referred to the role of other countries. There is another scheme set up by the International Convention for the Exploration of the Sea (ICES), whose secretariat is based in Denmark. It sets out a very detailed code of practice for introducing non-native and genetically-modified sea organisms into situations where they can spread to other countries. Under that system members of ICES may make applications for independent scrutiny by the ICES secretariat with experts before they carry out release. Many countries are members of the convention, including the United Kingdom. Indeed, genetically-modified algae were released on the north coast of America only after ICES had given its approval after scrutiny by other countries. There is a forum in which decisions are made in addition to our domestic and European legislation.

Lord Moran

474. The interbreeding of farmed salmon and wild salmon is not taking place only in Norway; it occurs in this country. As to the Otter Ferry experiment, I quite understand that it followed the procedure which you have described. As I understand the Scottish Office paper, when the Health and Safety Executive inspectors visited they found some aspects of the containment unsatisfactory and it was modified. That happened two or three times. But what struck me as odd about the whole thing was that it was an American company, AF Protein, who licensed the original organism and Canadian scientists who did the work. Yet they had to go all the way to Scotland because they were not allowed to do it in either the United States or Canada, though I accept that they may not have allied for a similar containment experiment in those countries. Does that strike you as strange?

(*Dr Smith*) It seems strange that one has to go to another country. However, the way that United Kingdom legislation is written means that organisations are allowed to keep and work on genetically-modified organisms provided they can satisfy the authorities that the safety precautions are satisfactory. In this particular case, after several inspections the inspectors found the containment facilities satisfactory. I am not sure what the Canadian

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authorities said, but the level of containment was considered satisfactory such that the fish could not escape.

Lord Jopling

475. I have the paper here from the Health and Safety Executive, paragraph 2 of which says: "It was apparently blocked by the Canadian authority due to the concerns about environmental safety." It is my conclusion that the company then thought that the Scottish Agriculture Department was a soft touch and came here to do the next step-by-step work following the laboratory trials carried out in Scotland. I suppose that, anticipating that they would find it difficult to release those salmon here, they said that they would be released in Chile. It seems to me that the Scottish Agriculture Department was treated as a soft touch in that these people could carry on with their work which was potentially enormously dangerous environmentally. If one is to breed salmon that are able to live in waters much too cold for native salmon and can grow at 22 times the normal rate, with 10 times being the average, the effect on existing fish stocks could be tremendous. Did ICES make an assessment of the effect of the release of these salmon on fish stocks and the general ocean environment?

(*Dr Smith*) As to the first question, the inspection by the Health and Safety Executive requires the containment facility to be adequate. These fish were being kept in tanks on land. The Government were concerned to ensure that these fish would not escape. Therefore, the containment level was increased before the fish were allowed to be brought into the country such that we were satisfied that they would not be able to escape into the wild from the experimental station. We would not permit these fish to enter our own natural environment. The way the legislation is framed is that provided the person keeping the animals can provide satisfactory containment facilities such that they will not escape we have no grounds to prevent them from being kept.

476. That is a matter of argument, is it not?

(*Dr Smith*) That is a matter of judgment on which we seek advice from the committee on the containment of animals. There are many organisms kept in containment that should not be allowed to be released into the environment. It is possible to engineer suitable containment such that the likelihood of escape is minimised.

(*Dr Parish*) ICES was aware of the work being carried out on the Otter Ferry salmon. Its primary concern was that the level of containment was sufficient to prevent any release into the environment. Its interest would have been increased in this case if it was felt that the level of containment was inadequate. It is hard to draw a comparison with why the Canadian authorities refused to allow the work to go ahead. One does not know under what circumstances the work was proposed. The proposal might have been that the experiment should be carried out in sea cages to mimic salmon farming conditions, whereas if a facility already existed where there was adequate land-based

containment perhaps it would have been judged that that was the best option for continuing the work rather than building a separate facility in another country. It is difficult for us to make comparisons and decide why the Canadians refused to sanction it. We do not know the circumstances of the application to carry out the work.

477. That does not answer the whole question. The background is that there was a proposal to breed a new type of salmon that could have a devastating effect on the whole oceanic environment. Did the Government consult ICES? Were the Government wise to allow the work to proceed at all? I remember years ago that certain breeds of cattle were smuggled into this country. It was perfectly simple. Having bred this type of salmon, it is perfectly easy to smuggle in fertilized eggs and then breed commercial quantities, with potentially devastating effects. How much thought was given to allowing this work to go ahead at all bearing in mind the devastating the effect on the ocean that may follow?

(*Dr Smith*) The Government considered this extremely carefully. A great deal of thought was put into this matter before the salmon were allowed to be brought over here and placed in containment. The containment facilities were designed such that the fish could not escape. If they cannot escape into the environment they do not pose a threat to the environment. The trade that you speak of would be illegal under United Kingdom law. We cannot cater for people taking part in illegal activity, but these fish were in tanks on land and the HSE inspectors were satisfied with the containment such that they could not escape into the environment.

Lord Willoughby de Broke

478. Do you not think that it is precisely this kind of concern, with the ramifications that Lord Jopling has described, that has given GM its current bad name? Surely, the Government should be more proactive (to use that terribly trendy word) in spotting deliberate error. These experiments cause an enormous amount of alarm for the very reasons given by Lord Jopling. Should not the department be more aware of and sensitive to such concerns in future?

(*Dr Smith*) Recently, there has been more concern about work on genetically-modified organisms than perhaps there was when the Environmental Protection Act was passed in 1990. But the basis of the Act is that companies are permitted to keep and do work on genetically-modified organisms provided they can satisfy the safety requirements to ensure safety for human health and the environment. Those detailed requirements are set out in the regulations. Whether that piece of legislation needs to be reviewed is a decision for Ministers.

Chairman

479. Would one or other of the advisory committees normally be consulted, and did that happen in this case?

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(*Dr Smith*) Two advisory committees would have given advice. One was the Health and Safety Executive Committee on Genetic Modification and the other was the Government's Advisory Committee on Releases to the Environment. We are able to ask them for advice. I am unable to tell you at this minute whether they were consulted in this particular case, but I can write and let you know. But it is always open to us to consult those advisory committees on any of these issues. In any case that is to do with releases into the environment the Secretary of State is required to consult the appropriate advisory committees.

480. Was there a requirement for such consultation in this case?

(*Dr Smith*) Unless the company applied for consent to release the fish ACRE would not have been consulted. However, my department is free to consult ACRE about any matter of concern. In this case the level of containment was considered to be satisfactory to prevent release.

Lord Wade of Chorlton

481. In the event, the containment proved to be satisfactory and there was no release. Your assessment as to the safety of the containment proved to be correct?

(*Dr Smith*) Indeed.

Lord Jopling

482. The European system for granting marketing consents has been extraordinarily slow. We understand that that has been due largely to political considerations and the variety of opinions among Member States. We have been told that this has had a harmful effect on the European scientific industry and on its agriculture. Are you concerned about what is happening in Europe? Are there any ways in which changes can be made to ensure that the process achieves what I regard as almost the impossible; namely, a more open, transparent, safe and speedy system?

(*Dr Smith*) There have been extremely long delays in the European Union in relation to marketing matters. If one takes experimental releases, they have all been considered within the United Kingdom statutory timescale. For marketing consent the timetable in the directive places a very tight time constraint on the countries that have to make the initial assessment: 90 days. The time for other Member States to consider the dossier is 60 days. If there is no agreement among Member States to allow the product to be given marketing approval it then goes into the Commission procedure. That is where the greatest delay takes place. The delay has been as great as several years. Ministers have been extremely concerned about this. My Minister wrote as recently as last autumn to the Commissioner of DGXI to complain about the time taken. The European Commission has started to move products forward. The impasse was resolved by the use of the European scientific committees. They are proposed to be brought into the

system under the amended directive. As to those marketing cases that gave rise to the backlog, the dossiers were submitted to the scientific committees who were able to give their opinion. Some of the products have moved through. The United Kingdom gave approval for marketing two products on 9 June of this year. That was concerned with the import of grain from North America. Under the existing directive we hope that matters are moving forward. The Commission's proposals for the revision of the directive will place a very strict timetable on the Commission for the following stages if Member States cannot agree. If and when the amended directive is adopted the situation should improve. In answer to your question as to how we can ensure that there is an open, transparent and quick process, this is a very difficult issue. As to openness, the Government have public registers for all the applications for marketing consents. We also make available the whole dossier to the public, although we keep confidential any commercially sensitive material. Usually once the product has come onto the market the question of intellectual property rights has been settled. The advisory committee's advice is made public. We are taking further steps to ensure that is made transparent. But the decision process within the European Union perhaps needs to be made more transparent. That is one of the matters that will be addressed in the amendment of the directive. This is an extremely controversial area. Certainly, there is not full agreement among the public as to whether these products should be put onto the market. At present the authorities are assessing the safety for human health and the environment. Whether people want these products is a different issue which is outside the regulatory process.

Lord Gisborough

483. Due to objections to this technology by a number of Member States, might subsidiarity be used to take the heat out of the problem, perhaps for growing if not for marketing? Would it be more practical for Member States to opt out after EC approval or for Member States to be allowed to give their own commercial consents?

(*Dr Bell*) The plain fact is that under EU treaty rules there are no grounds for Member States to be allowed to grant their own consents. That would conflict with the single market arrangements for trade within the Union. That option is not therefore currently open to us. However the Government see no reason to stop the cultivation or use of GMOs where they have been approved for sale following a full safety assessment. They would not wish to operate on any other basis. A ban on non-safety grounds would be very likely to be open to challenge under the rules of the World Trade Organization because a ban on cultivation effectively amounts to a ban on trade in the seed. The Government are aware of the very wide range of public opinion in relation to genetic modification. For that reason they have initiated a public consultation exercise that is about to get under way, the preliminary work having now been

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DR JON BELL, MR NICK TOMLINSON,
DR LINDA SMITH and DR BILL PARISH

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[Lord Gisborough *Contd*]

completed. This aims to explore people's views in more detail and is being organised by the Office of Science and Technology which comes under the control of Mr Battle. The intention is to get behind the media headlines and find out what the public are concerned about and, more importantly, why. We do not understand fully at this stage the principal concerns. We hear a lot about a wide range of concerns, but it is necessary to carry out a more detailed analysis to discover exactly what the concerns are and the basis of those concerns. As far as the farming community is concerned, we are very well aware that it has raised concerns about not being able to have access to the technology within the same timescale as others. That must also be weighed in the balance. The general view is that it is difficult to see how policies requiring farmers to grow less cost-effective varieties than those being used elsewhere can be sustained beyond the short term in a world trade situation. A number of factors therefore have to be taken into account. Our room for manoeuvre is fairly limited because of European Union and, more particularly, world trade agreements.

Lord Grantchester

484. Turning to the pattern of international trade, we have already seen problems arising from different attitudes and speeds of development of this technology notably in Europe and North America. The European position in relation to GMOs is constrained by the Convention on Biological Diversity and the World Trade Organization. What do you see as the detrimental aspects of the current restraints of these agreements? What international developments are most necessary in the near future?

(*Dr Smith*) To start with the Convention on Biological Diversity, that convention requires the contracting parties to establish means of regulating or controlling the risks associated with the use and release of what are called living modified organisms which are likely to have adverse environmental and human health impacts. The EC legislation covering GMOs serves to implement this requirement under the convention. The Government do not see the obligation as a constraint but as a welcome measure that will foster the safe use of biotechnology worldwide through the exchange of information. The current major constraint of WTO rules is their lack of clarity as to how parties can invoke general exceptions under Article 20 of GATT which is concerned with human, animal or plant health. The developing case law is helping but it will take time to establish clear ground rules. The international development most necessary in this area is the conclusion of the negotiations on the bio safety protocol which has been worked on under the Convention on Biological Diversity. The final meeting on the protocol is planned for February of

next year. This was agreed by the contracting parties to the convention in May of this year. We hope that there will be rapid implementation of that. That will help to promote safety and avoid the creation of trade barriers.

(*Dr Bell*) Referring to the World Trade Organization rules, the SPS agreement is currently being reviewed. The present position of the Government is that they do not expect a significant change in the way that that operates in terms of its dependence on scientific information. That is still considered to be the most effective way in which the agreement can work on a worldwide basis. Constraints are built into that to take other matters into consideration. Having said that the rules are based on science they do embody the right of countries to set their own level of protection, provided that that can be justified scientifically. It also allows for precautionary action to be taken. It is considered to be a reasonable basis on which to operate. No particular changes are likely to be sought in that respect.

485. Do you think that it will lead to a greater degree of compatibility between the two regulatory systems?

(*Dr Bell*) One would like to think so but it may be optimistic to make that assumption, certainly in the short term. We have not seen a great deal of that so far in this particular area, but it may be that as experience develops and GMO technology matures there will be an easier passage of products between the various trading blocs and more agreement as to how they should be assessed. A good deal of the problems so far have arisen because it is a new technology and one particular trading bloc has embraced it more enthusiastically than others. We wish to take a cautionary approach. But in the fullness of time it may be that the two sides will move closer on how the technology should be developed. Whether or not that will be spurred on by agreements of this nature is another matter. I am inclined to believe that that will happen independently of these agreements, although obviously all countries are expected to abide by them. The Government are determined that the United Kingdom will abide by the agreements to which it has signed up.

Chairman] That brings us to the end of the questions that we have time for this morning. Perhaps you would be so kind as to supply us with written answers to the outstanding questions which we will supply and would have asked given time. You also said that you would be willing to provide some additional material. There are a couple of subjects on which it would be helpful to have the text of ACRE's advice: one is the story of the lacewing and the other is the proximity of the organic farm in Devon to a GM crop. Thank you very much for coming here and giving us extremely useful evidence.

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Supplementary Memorandum by the Ministry of Agriculture Fisheries and Food and the Department of the Environment, Transport and the Regions, and on behalf of The Scottish Office and The Welsh Office.

SEGREGATION

11. *Is segregation something which should be left to the market, or is there a role for government? What about traceability? Is it feasible, desirable or indeed essential? Earlier this year, MAFF published a list of non-gm soya suppliers. To what extent does MAFF go to ensure that this soya is indeed non-gm. Is this a justifiable role for government? Iceland is sourcing their non-gm soya from Brazil. Do you believe that Brazilian soya is indeed non-gm?*

All GM varieties for use in Europe have been approved following a full safety assessment. Imposing segregation as a condition of approval would breach the TBT Agreement because it would be more trade-restrictive than is necessary to meet its objective (since consumer choice can be assured by requiring labelling, which is less trade-restrictive than segregation). Equally mandatory segregation could not be defended using the SPS Agreement, because it would not be a measure to protect health (since a product that is approved for marketing has already been assessed to be safe). The Government recognises that there is a demand for supplies of non-GM ingredients and market forces are responding to this by means of identity preservation at a commercial level. Indeed there is already evidence that this is happening, for example Iceland Frozen Foods are offering non-GM products, other supermarkets are also moving in this direction. MAFF recently produced a list of non-GM suppliers to help smaller companies. This list now stands at 57 suppliers. However, the Government has made it clear from the outset that it is for companies to satisfy themselves that the product that will be supplied is likely to meet their requirements before placing orders. The role of the Government is to ensure that the necessary legislation exists to check that foods are correctly labelled where they contain GM material and that this is appropriately enforced.

The Government is aware that Iceland Frozen Foods is sourcing some of its soya from Brazil. As yet Brazil is not growing GM soya commercially, however, soya crushing plants in Brazil are known to process US soya in order to operate at full capacity. The Government understands, however, that Iceland obtains its Brazilian soya from an inland area and that they also have procedures in place to ensure that the processing plant does not process GM soya.

LABELLING

12. *What is the latest state of the Council negotiations on labelling? Is this the final word on the subject? If not, what remains to be negotiated? Should labelling go further than stating that a product is GM, and state the purpose of the modification, as is the case in Canada? What should be labelled (DNA, protein)? Should labelling on foods be required to the extent that the labelling can be verified by testing? What thresholds should be set?*

The EC novel foods regulation 258/97 came into effect on 15 May 1997. In addition to requiring a pre-market safety assessment this regulation contains specific labelling rules for novel foods which apply in addition to existing Community labelling requirements for foodstuffs as set out in Directive 79/112/EEC. The Council regulation 1139/98 on GM soya and maize labelling comes into effect on 1 September. The regulation requires labelling based on the presence of novel protein or DNA and is consistent with the labelling rules in the novel foods regulation 258/97 where a food is labelled if it is no longer equivalent to a conventional counterpart. Member States agreed unanimously that the presence of novel protein or DNA should be the trigger for labelling. To improve transparency a "negative list" is being developed of food ingredients that do not contain novel protein or DNA. In addition discussions will continue on the practicality of setting a *de minimis* threshold to ensure that labelling is not triggered by very low level adventitious contamination. In agreeing the text Member States also invited the European Commission to encourage the development of validated methods for the detection of protein or DNA resulting from genetic modifications.

The Government is aware of the Canadian proposal for labelling issued in April 1997 which includes a provision for voluntary positive labelling to indicate that a novel food has particular attributes resulting from genetic modification. This is consistent with the labelling of tomato puree in the UK which includes a voluntary description of why the tomatoes were modified. Under the Canadian proposal where there is compositional difference or a health or safety issue which triggers mandatory labelling, then that labelling will require identification of the attribute rather than the fact that the product has been genetically modified (e.g., high laurate canola).

The Government recognises that in many cases a company will wish to indicate why a product has been modified and this is allowable under the legislation.

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PUBLIC CONFIDENCE

13. *Do you have any proposals for improving public confidence in the regulatory system? MAFF would appear to have lost the confidence of the public, Brussels has a poor public image, the regulatory committees are invisible. Is greater transparency part of the answer? How can this be achieved without causing harm to the process itself?*

The Food Standards Agency Bill will be published shortly setting out proposals designed to restore consumer confidence in the regulatory system. Much has already been done. For example the advisory committees are now publishing minutes of their discussions, making their annual reports more widely available (the ACNFP 1997 annual report was placed on the internet last week) and holding meetings in public wherever possible. MAFF has also co-sponsored an exhibition developed by the Science Museum to explain the issues involved with GM foods.

Improved transparency can help allay concerns, but consideration also needs to be given to what the underlying reasons for concern are and, as mentioned in the reply to question 9, steps are about to be taken to examine this in more detail.

PRODUCT LEGISLATION

14. *For trial releases, will anything be lost, or what might be lost, in the move from horizontal (GMO) to vertical (product) legislation? Expertise? Would this be appropriate for commercial release too?*

Does the application of the criteria for safety of novel foods to field trials where environmental risks are likely to be the major problem diminish trust in the risk assessment process?

How is the environmental safety of novel foods that contain viable modified organisms assured?

This was to a large extent addressed in the oral evidence in response to the question on the revision of 90/220/EEC.

A key concern held by the Government is the proposal to remove from the scope of the directive those products under development which are covered by Community legislation which provides for a specific environmental risk assessment similar to that in this directive. The Government is concerned that this could have the result of environmental effects not being taken adequately into account because of the need to weigh them against other considerations addressed under product legislation. The Commission's proposal does not include any role for the 90/220 competent authorities in the assessment and decision-making for GMO products under development; the competent authorities' expertise on environmental risk assessments for the deliberate release of GMOs might therefore not be drawn upon. This would not encourage public confidence in the regulatory regime. Further, the proposal would not be helpful for those wishing to conduct research releases because it would add to the complexity of gaining a consent: one such release might require several approvals, and this could also result in a longer time than the current maximum 90 days before all proposals were granted.

As regards commercial releases, the Commission has strongly advocated a "one door, one key" policy, whereby there would be only a single regulatory entry point for access to the Community market. Only three Community instruments have been adopted so far which remove GMO products from the scope of 90/220: the medicinal products regulation (2309/93), Commission Directive 94/40/EC amending Council Directive 87/153/EEC fixing guidelines in the assessment of additives in animal nutrition and the novel foods regulation (258/97); others, such as amendments to the seeds directives and a novel seeds regulation, are under negotiation or are planned. Each of these, in providing a derogation from 90/220, requires that necessary consultations be held with the bodies set up by the Community or the Member States in accordance with Directive 90/220. However, none of the instruments sets out procedures for the consultation or provides a mechanism to take into account the overall view of the 90/220 competent authorities. This has not presented difficulties up till now because only one notification to market a product under these instruments has been submitted. However, given the likely trend in the development of GMO products, the Commission and the competent authorities are seeking to introduce appropriate administrative mechanisms.

While the "one door, one key" policy might be desirable in principle, the implications of the regulatory requirements and the administrative practicalities need to be considered. For example, if product based legislation is adopted at the expense of horizontal regulation for research and development trials crop plants may require approvals under more than one instrument, depending on the final uses of the crop. For example, a particular line of genetically modified wheat would be likely to require separate approvals under the seeds, novel foods and animal feeds legislation.

Does the application of the criteria for safety of novel foods to field trials where environmental risks are likely to be the major problem diminish trust in the risk assessment process? How is the environmental safety of novel foods that contain viable modified organisms assured?

We understand this question to be associated with the first of the two additional questions posed by the Lord Ray (see question 26).

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TRANSPARENCY V CONFIDENTIALITY

15. *Regulatory transparency has to be balanced with commercial confidentiality. This is of especial concern over intellectual property and eco-terrorism. Is either the publication of dossiers or the exact location of field trials unwise? Are you considering any changes?*

In submitting dossiers for application to release or market genetically modified organisms, applicants can indicate information which they consider to be commercial in confidence. The extent of such information is subject to review by and agreement of the Secretary of State before the application proceeds. The GMO deliberate release regulations prevent information agreed by the Secretary of State to be commercial in confidence from being released or published. Applicants are required to inform the Secretary of State once information is no longer commercial in confidence.

Under the directive and the UK legislation, the location of field trials may not be kept confidential and this is part of the information required to be placed on the Public Register. One of the purposes of making this information public is to inform those in the neighbourhood of proposed release sites. It is regrettable that this information has also been misused recently by direct action protesters to locate and vandalise field trials of genetically modified crops. These trials are necessary in order to answer many of the questions that pressure groups and others have raised. Ministers have condemned these attacks but the scope for further action under the current legislation is limited. It is the responsibility of consent holders to safeguard their sites and they may involve the police to assist them where appropriate.

The government is not, at present, considering any changes in the current arrangements.

GAPS IN THE REGULATORY PROCESS

16. *Have you identified any gaps in the current regulatory process which you are keen to see filled?*

The current legislation covering contained use, deliberate release and marketing of products provides a comprehensive package of controls to ensure protection of human health and the environment. There are no obvious gaps. However as described in the oral evidence in response to the question on animals, the Government proposes to strengthen the controls on the contained use of plants and animals by making additional provisions for notification.

Concerns have been expressed that wider environmental issues associated with the commercial introduction of some GM crops may not be adequately covered. In practice, the environmental risk assessments carried out for the GMO legislation taken together with the pesticides legislation where appropriate should address such issues and no distinction is made between the agricultural and the natural environment. However the Government is reviewing whether there are any other environmental aspects which are not being addressed under the current regime.

From the administrative point of view the Advisory committees have broad terms of reference and can also recommend that specific issues are taken forward by Ministers. On the food side the Food Advisory Committee had its terms of reference enlarged last year to enable it to consider any food related issues not considered by other committees.

GROWING CONDITIONS

17. *Within the US and EC, conventional crops are sometimes limited to particular geographic areas (or states) due to geographic concerns (wheat and absence of weedy relatives/potatoes and climate). Why might a GM crop be unsuited to growth in the EC or vice versa? Could this be done for GM crops on more political grounds?*

The Government is not aware of any instances where, for climatic reasons, a GM crop would not be suited to cultivation in the EC unless its non-GM counterpart was similarly constrained. There may be situations where farmers may not need to grow some disease resistant GM varieties if the disease is not prevalent in a given location. The Government is also aware of concerns associated with the cross pollination of GM herbicide tolerant crops with weedy relatives. Following publication of a discussion paper last year the Government will be making an announcement on proposals for the management of GMHT crops shortly.

REFUGES

18. *Refuges have been recommended as a way, for example, to maintain insect populations and to slow down the development of immunity to GMHT and GMPR crops. Should refuges be statutory or voluntary?*

One of the concerns expressed about widespread commercialisation of insect resistant GM crops is that it may encourage the development of resistance breaking insect populations. In areas of the United States where

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Bt cotton and Bt maize are grown widely, refuges of non-GM crops are employed to maintain a "bank" of non-resistant insects in the population. Population modelling and field work indicate that this works to delay the emergence of widespread resistance.

Experience suggests that refuges are most effective in warm climates where target insects undergo several generations in one season. In temperate Northern Europe, including the UK, they may have little value. The Government has not yet formed a view as to whether such refuges are necessary nor whether they should be voluntary or statutory. More research is required in this area to evaluate the potential threat of resistant insects and to formulate effective measures to prevent or delay the selection of resistance. Although experience from managing resistance in existing agricultural practice suggests that effective measures can be found. This will help to identify the specific need for and extent of further research. Based on this, guidelines for best practice could be produced as they have been of other issues by the farming industry's Supply Chain Initiative for Modified Agricultural Crops (SCIMAC).

ZONING

19. *It has been put to us that the growing of GM crops might be limited (voluntary or statutory) to particular areas within Member States, either to protect particular biodiversity or to assist segregation as value-added modifications are introduced. What is your view on such zoning?*

The Government has no legal powers to apply additional conditions to marketing consents for GM crops. However, as has been mentioned in reply to question 17 the Government will be making an announcement on the management of GMHT crops shortly.

FARMS SAVED SEED

20. *The best way to prevent a super weed is by making plants male sterile. This would end the practice of farmers saving up to 30 per cent of their seed. The same effect could be enforced contractually. Is this a change the Government would be concerned by?*

We were told by the American Soya Bean Association representatives that until the advent of the Bt Soya bean they had kept up to $\frac{2}{3}$ of the seed sown in each year, and only purchased approximately $\frac{1}{3}$. Their contracts do not now allow them to keep any seed at all. The introduction of hybrid varieties, which cannot be kept as the yield drops substantially after the first year, or of male sterile seed would mean that farmers could not keep seed effectively. Should this be a concern?

United Kingdom and European Union plant breeders' rights legislation* specifically provides for farmers to save seed of the main agricultural species which have historically been farm saved in the EU (e.g., cereals, potatoes, oilseeds). In addition, the recently adopted Directive on the Legal Protection of Biotechnological Inventions contains a provision which states that farmers can use farm saved seed containing a patented invention, without this use constituting infringement of the patent. This applies to the same extent and subject to the same conditions as Community plant breeders' rights. These provisions aim to strike a balance, which we would wish to encourage, between the use of farm saved and certified seed.

We have no experience of the contracts which American companies are said to use to control the use of farm saved seed. The nature of the seeds market in the UK is such that plant breeders do not normally enter into direct contracts with individual farmers. Seeds merchants are licensed by plant breeders to deal in protected varieties and it is the merchant who sells seed to the farmer to produce a commercial crop.

The farm saved seed provisions do not extend to seed saved from a crop grown from a hybrid variety, but a crop resulting from such seed would have limited value. There are also a range of varieties available to farmers. Hybrids are common in the oilseeds sector, for example, but there are still plenty of non-hybrid oilseed varieties for a farmer to select, which can be farm saved.

* See the Plant Varieties Act 1997, s.9 and Council Regulation 2100/94, Article 14.

ANTIBIOTIC RESISTANT MARKER GENES

21. *How concerned is the Government by the use of antibiotic resistant marker genes? Have you recommended a phase-out?*

The presence of antibiotic resistance marker genes in Genetically Modified Organisms released to the environment has been considered by the Advisory Committee on Releases into the Environment (ACRE). In particular, the committee has reviewed the presence of antibiotic resistance genes in genetically modified plants and examined the potential environmental safety issues, including the possibility of gene transfer to soil microbes. ACRE have concluded that the risk to human health and the environment from the current markers

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(mostly for kanamycin and ampicillin resistance) is low. This is primarily because of the prevalence of antibiotic resistance that already exists in the environment. Any addition made to this resistance background that might result from the release of GMOs will be negligible.

That said, ACRE is concerned that resistance markers for antibiotics which have an important role in medicine are not used in GMOs to be released. Further, the committee has recommended that in principle, products which come to the market should not contain material (including marker genes) which does not contribute to the modification for which the product is being marketed. This is not for safety reasons but for the sake of good practice as the marker genes have no function in the final plants.

The Advisory Committee on Novel Foods and Processes (ACNFP) has examined the concerns raised in connection with the use of antibiotic resistant marker genes in considerable detail and has produced two reports. Copies of the ACNFP reports are enclosed. [not printed]. The Committee's overall conclusion was that the use of antibiotic resistance marker genes should be considered on a case by case basis taking into account:

- the clinical use of the antibiotic;
- the likelihood of transfer into and expression in gut micro organism; and
- the toxicity of allergenicity of the gene product.

The ACNFP also recommended that those developing food GMOs should develop alternative markers or find ways of removing those used. There is evidence that companies are starting to act on this recommendation.

RESEARCH

22. *English Nature have based their call for a moratorium on the fact that research is needed into the effects of GM crops. What research has been commissioned and when are results expected?*

What is the impact on wildlife of GM crops? Are you funding research in this area? If not, why not? If yes, when are the results likely to be published?

The reduction in the volume of herbicide that needs to be used is well known, and is arguably good for the good for the soil and consumer, but what impact on biodiversity has there been?

What is the impact on wildlife of GM crops?

The DETR has funded a programme of research since 1987 into the issues and implications raised by the release of GM crops into the environment. Results of research programmes are published as Research Reports and are widely available from the DETR publications sales centre. The scope of the published projects relating to the possible impact of GM crops are summarised below.

Report no. 1.—*Genetically modified crops and their wild relatives—a UK perspective*—assessed the likelihood of transgenes being transferred from genetically modified crops to wild species growing in the UK. This included, where relevant, establishment of the crops themselves as feral applications.

Report no. 8. *Gene flow in natural populations of Brassica and Beta*—addressed the issue of transfer of modified genes between crops and wild relatives. Such information is important in evaluating both the potential for the escape of transgenes, and the environmental risk assessments of each release.

Report no.9. *Selectable marker genes in genetically modified organisms*—evaluated the potential hazards of the use of selectable markers in plants, microorganisms and animals intended for release into the environment.

Currently there are three ongoing research projects that should provide additional information on the environmental impact of growing GM crops. These projects are:

Environmental impact of insect resistance in GM plants. Completion date December 1999.

Impact of multiple tolerance in GM plants. Completion date December 1999.

Environmental impact of disease resistance in GM plants. Completion date September 2000.

In addition to these three projects, another project is planned to investigate the *Environmental risks of stress tolerance in GM plants*. The aim of this is to provide more information to help evaluate the risks of the release of such plants. This project is planned to be completed in September 2001.

In 1990 MAFF started a programme of research to look at the possible risks to the agricultural environment from the release of genetically modified organisms. Over £3.5 million has been committed to the programme and, to date results have not indicated any risks to the agricultural environment from the release of GMOs. In 1997, new research on the risks to the agricultural environment from the release of herbicide tolerant crops was commissioned with a total budget of over £500,000. A list of some of the work covered in the herbicide tolerance projects is given in paragraph 13 of the original briefing submitted to the Committee.

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The impact on wildlife of the release of GM plants has, thus far, been negligible. The releases conducted to date have been for experimental purposes and are only approved after a rigorous risk assessment has indicated they will be safe. Over 300 field trials of GM crops have been carried out in the UK and the post trial monitoring has demonstrated that none of these has resulted in harm to the environment.

The wider implications of the commercialisation of GM crops for wildlife is the subject of current debate, particularly the possible reduction in farmland biodiversity that changes in agricultural practice may cause. The results from DETR funded research projects provide valuable information on a number of possible environmental issues that may arise from growing GM crops. None of the results obtained so far, either from completed projects or those ongoing, give cause to believe that the GM crops studied will necessarily be any more damaging to the environment than conventional agricultural practice.

The Government is working with the Advisory Committee on Releases into the Environment and Conservation Bodies, including English Nature and RSPB, to address their concerns about impact on wildlife and find a way forward. This consultation is focusing on the wider implications of GM crops and their possible effect on wildlife. This will highlight areas in which further research is needed and help to formulate the most appropriate questions to be addressed.

LIABILITY

23. *In the event of something going wrong with a GM crop, who would be responsible? Is this an issue that concerns you? Would this be different if it were a food or feed product?*

Civil liability for damage caused by a genetically modified organism is governed by the Common Law as developed by the courts. On the basis of Common Law principles, the firm holding the marketing consent for the genetically modified crop may be liable in law for any damages arising from ill effects attributed to the crop. Depending on the facts of the case the statutory regime for product liability may also be relevant.

The issue of environmental liability is an important one and the principal that those who damage the environment should pay for remedying the damage caused is one that the Government supports.

The Government understands that the European Commission intends to issue a White Paper on liability for environmental damage. This may include the question of damage caused by genetically modified organisms. The Government will study the detail of the Commission's proposals before reaching any conclusions on this matter.

The Government is of the view that in the event of something going wrong with a GM crop the company that holds the marketing consent for the crop would be liable. Indeed an applicant is already required to report any information which might affect the original risk assessment.

The Government supports in principle the proposal in the European Commission Green Paper on Food Law to extend product liability to primary agricultural produce and agrees that the extension of product liability to primary agricultural produce should be considered afresh, but the full implications must be explored before any final decisions are taken. It is important that the liability for producers is matched by the reasonable defence of due diligence.

NOVEL FOOD RISK ASSESSMENT

24. *Is risk assessment for novel foods an EC process or for Member States?*

The risk assessment for novel foods is initially undertaken at Member State level. An application is submitted to the Member State where a product is intended to be marketed first. That Member State has 90 days to provide an initial safety assessment. This initial assessment is then considered by all Member States within 60 days. If Member States raise objections or identify the need for a more detailed assessment the application is considered further under a centralised authorisation procedure. Final approval is therefore a matter for the Community as a whole. The European Commission produced guidelines on the safety assessment of novel foods to accompany the Novel Foods Regulation 258/97. A copy of the Commission guidelines and the electronic version developed in the UK are enclosed. [not printed].

IMPORTED GM FOOD INGREDIENTS

25. *The regulations at present are causing a stockpile of food, predominantly from the US. What approvals do imports require? Do they require an environmental assessment? Is this necessary where they are only to be imported for food use? How may the system be speeded up without any extra risk to the consumer or the environment?*

Where a GMO is intended to import solely for processing into food products approval is only required under the EC Novel Foods Regulation (258/97). If the crop is to be grown in Europe approval is also required under

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Directive 90/220/EEC. Under both sets of legislation an environmental risk assessment is required for viable material, e.g., grain, which could be grown in Europe. If the crop is only imported for food use an environmental risk assessment is still required to assess the impact of accidental spillage during transport. The Government is seeking to speed up the approval process without compromising safety. The Commission's proposed revisions to Directive 90/220 should help in this respect. In addition the Government is encouraging companies to submit applications in the US and EU in parallel rather than in the sequential way that has so far predominated and lead to many of the stockpiling problems referred to.

Additional questions posed by Lord Reay

26. *For commercial release, the directive exempts GMOs for which product legislation exists. There is a novel foods regulation. Would an application to grow and to use for food, for example a frost-resistant wheat, be subject to both 90/220 and the novel food regulation?*

Directive 90/220 and the Novel Foods Regulation operate in tandem: Consent would be required under 90/220 to sow, cultivate and harvest a genetically modified crop, and, at present, to use it as an animal feedingstuff. Under the Novel Food Regulation, consent would be required in order to market novel foods consisting of the genetically modified crop plant or derived from it. Both instruments require an assessment of the risks to the environment and to human health. However, while the scope of the environmental risk assessment under 90/220 must address all the risks associated with all the release activities, that is, sowing and cultivation, etc., the assessment under the Novel Foods Regulation needs only to cover any aspects that would involve release to the environment of the novel food itself. Usually there will be no such release, or a very limited release. Therefore the scope of the risk assessment is tailored in each case to the activities governed by the respective instrument. There can therefore be trust that together, the instruments provide for a comprehensive assessment of the risk.

27. *The Commission has proposed ending the use of PVC. If a plastic duck is made from a plastic produced in a GM plant and contains the gene product, would it need to be labelled as GM? Would it be subject to monitoring and potential seven year recall?*

Under current EC legislation the seeds from such GM plants would have to be labelled, however the plastic duck made from them would not, as the only non-viable products that have to be labelled as genetically modified are those food products which contain genetically modified material. The plastic derived from the GM plant would not be covered by this legislation, or by Directive 90/220/EEC. The plants growing the plastic would be subject to the proposed monitoring and potential seven year recall but not the ducks themselves.

WEDNESDAY 22 JULY 1998

Present:

Gallacher, L.
 Gisborough, L.
 Grantchester, L.
 Jopling, L.
 Rathcavan, L.
 Reay, L. (Chairman)

Wade of Chorlton, L.
 Willoughby de Broke, L.
 Young of Old Scone, B.

 Clanwilliam, E.

Written material from Professor Mark Williamson, Professor Emeritus of Biology, University of York

(Professor Williamson supplied the Committee with a chapter of a book, an article and a book review)

THE RELEASE OF GENETICALLY ENGINEERED ORGANISMS—BIOLOGICAL INVASIONS, CHAPTER 6.5

There is some dispute about whether the study of invasions is relevant to the assessment of risks from the release of genetically engineered organisms. So, first, what are these organisms and why should there be risks?

Molecular genetics now allows a gene to be taken from one organism and inserted into some totally unrelated one. Bacterial genes can be put into plants, arthropod genes into viruses. There are, of course, limits on what can be done but, as the subject is moving fast, I will not dwell on them here. This transfer of genes is commonly called genetic engineering. The current fashion is to refer to genetically modified organisms, or GMOs, rather than genetically engineered ones, and that is followed in official documents. For scientists, there is no reason to prefer an ambiguous and obscure term to one that is reasonably precise (Williamson, 1992). Genetic modification is a term that can be applied to all genetic programmes, and has no obvious association with restriction enzymes and the other tools of molecular geneticists. Genetic engineering is less ambiguous, and gives the flavour of experimental manipulation, so I will use it here. It is also the term used in US Congress OTA (1993).

Genetic engineering can be used to make organisms with new properties that may be commercially useful. In crop plants, herbicide- and pest-resistant varieties are being developed in many species. It is possible to change the nature of the crop product, changing the composition of the oil in oil seeds, manipulating enzymes so that tomatoes do not go squashy, and many other features. Pharmaceuticals could be made in plants or produced in milk. Fish can be made to grow faster (US Congress OTA, 1993; Krattiger and Rosemarin, 1994).

In principle, any commercially desirable trait could be added or enhanced. It is not surprising that much research has been funded, and that many commercial releases are near. On Krattiger's (1994) count there have been 2,053 field trials of transgenic plants world-wide up to mid-1994, and that, even allowing for differences in the definition of a trial, is fairly certainly too low (Anon, 1994b). Although almost all OECD countries have some form of regulation, others outside the OECD such as China and Israel apparently do not. Regulation, such as the European Union's directive 90/220/EEC, is likely to keep only a few, rather obviously undesirable, products from the market. It is reasonable to assume that there will soon be many different genetically engineered organisms marketed in large numbers world-wide.

Will there be ecological and environmental change from genetically engineered organisms? Russo and Cove (1995) give a good overview of all the benefits and hazards from these techniques. Invasions show that damage can happen when an organism finds itself in a new environment. For a novel genetically engineered organism all environments are new. A familiar case where a change to a new environment, accompanied by a small genetic change, has had quite unforeseen terrible effects is AIDS. Maybe some day a genetically engineered organism will produce a major, but quite different, disaster.

Human AIDS is caused by two viruses, HIV1 and HIV2. These are closely related to a group of viruses found in other primates, the Simian Immunodeficiency Viruses or SIVs (Morrison and Desrosiers, 1994). These are all single-stranded, encapsulated RNA viruses, retroviruses. Being RNA viruses, they are far less stable genetically than DNA organisms. Various strains in one virus have 80 to 100 per cent identity, closely related retroviruses attacking other species have about 80 to 90 per cent identity, more widely related ones 55 to 60 per cent. It would seem that both HIV2 and SIV_{mac} (which infects captive macaques, *Macaca*) are derived from SIV_{smm} (which infects the sooty mangabey, *Cercocebus torquatus*). Similarly, HIV1 is closely related to SIV_{cpz} which is found in chimpanzee *Pan troglodytes*. SIVs in wild monkeys and apes are, as far as is known, non-pathogenic. Rhesus monkeys *Macaca mulatta* with SIV_{mac} develop an AIDS-like disease. Pigtail macaque *M. nemestrina* with the same virus are killed in a week or so. Small genetic changes and a new environment can produce very drastic effects.

As I said at the end of section 5.3.1, major invasions may come out of the blue at any time. Will genetically engineered organisms add to these problems?

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Some proposals, such as the engineering of non-specific biological control viruses, are evidently bad practice (Williamson, 1991), but the unnecessary risk comes from the nature of the virus, not the genetic engineering. It is often asserted that for most commercial genetic engineering, the invasion model is not appropriate. For instance, with crop plants, the argument is that the plant is familiar, the new variety will have to undergo extensive performance trials, and the genetic novelty is more precise and better understood than the genetic novelty produced by traditional breeding programmes. Hence the release of genetically engineered plants is different from other invasions. It is also sometimes stated that many changes are needed to change an organism into a weed or a pathogen (National Academy of Sciences, 1987).

The unsatisfactory points in that argument are covered in earlier sections of this book. Although the crop plant is familiar, and the genes inserted are well known, the combination is novel. There are no universal characters that distinguish weeds and pathogens from their harmless relatives (section 3.3.2), and the genetic differences between invasive species and those that fail to invade may often be small (section 6.2). In fact, many plants have become weeds merely by being taken to new regions. It is not surprising that ecologists think that aspects of the invasion model are relevant to the risk assessment of genetically engineered organisms (Tiedje *et al.*, 1989; Altmann, 1993; Shorrocks 1993; US Congress OTA, 1993; Seidler and Levin, 1994). It is an appropriate model.

Even in those countries where there is effective regulation of small-scale trials, the study of invasions suggests that the probability of detecting undesirable products at an early stage is not large. Many pest invaders have not been recognised as such for many years, often decades, *Impatiens glandulifera* (section 1.3.3) and the muntjac deer (section 5.1) for example. On the other hand others, such as zebra mussel (section 5.4) were recognised as problems almost immediately, but spread so fast that it was difficult to limit the damage. As those genetically engineered organisms that become problems will usually be commercial products, they will mostly be widespread quickly, and difficult to control whether the problem arises soon or not.

Some problems may well be delayed. Texas cytoplasm is a possible example of how this could happen; it is a genetic modification of corn, *Zea mays*. In corn, male sterility is a most useful agronomic trait, because it allows controlled breeding without the work of removing the male inflorescences, the tassels. Texas Cytoplasm varieties are male sterile because of a change in a mitochondrial gene (Levings, 1990). Remarkably, the same molecular mechanism that made the plants male-sterile also made the plants susceptible to a fungal pathogen, *Bipolaris maydis* race T. About two decades after the gene, T-urf13, came into commercial use, the fungal disease devastated the corn containing that gene, which was by that time 85 per cent of the US corn hectareage, and made the innovation useless. The molecular details were known, the pathogen was known, but the interaction was not predicted and the consequences did not appear until the new genotype was in full commercial use. It seems optimistic to suppose that similar failures will not happen in future, however the regulatory system is designed. Without regulation they might even become common.

Texas cytoplasm was an agronomic problem. Will there be ecological and conservation problems? There are two classes of possibility. One is the spread of the genetically engineered organism itself, the other is the spread of the engineered gene in wild relatives of that organism (Raybould and Gray, 1993). As with all invasions, and bearing the tens rule in mind (section 2.3), it is reasonable to say that neither will happen frequently. Pests arise in around 1 per cent of organisms introduced at random. If regulators can control excessive commercial enthusiasm, the frequency could be much less (Williamson, 1988); that is taking an optimistic view of the effectiveness of regulators and regulations. But whatever the proportion, the number of proposed products is so large, that some ecological damage seems likely, though it may not be apparent for some decades.

Perhaps the most remarkable general feature of invasions is how unpredictable they are. One possible gain from the release of genetically engineered organisms may be a better understanding of why most genetic variation seems to have no relation to invasion success, but nevertheless some genes are important.

Can the risks from transgenic crop plants be estimated?—*Tibtech*, December 1996 (vol. 14)

Companies have been developing transgenic plants for a decade or so. Some lines and some products are getting into commercial production. On supermarket shelves there is a tomato paste that declares itself to be genetically modified (i.e., transgenic). Companies have also been complaining about the tiresomeness of European regulation. Although pressures of trade, and from the OECD, will make rules increasingly similar worldwide, the European political structure has its own distinctive effect. Proposals for commercial release are first assessed by the "competent authority" in one member state. If a favourable opinion is reached, the proposal is sent to the competent authorities in the other member states. At this stage, objections can be raised, as illustrated by two transgenic plant lines that have run into trouble when voted on at the European level.

The first transgenic plant line was PGS's herbicide tolerant oil-seed rape (*Brassica napus*). Although it was approved for production¹, but not for human or animal consumption, several Scandinavian states had objected because of the implications for the use of herbicides². The European Commission decided this objection was "not within the scope of" the Directive¹. There appears to be a gap in the regulatory system, which may cause

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problems when proposals bridge the scopes of two different Directives, 91/414 (pesticides) and 90/220 [release of genetically modified organisms (GMOs)].

The second transgenic plant line was Ciba's corn-borer tolerant maize (*Zea mays*), which also contained a gene for herbicide tolerance and a gene for an antibiotic marker under a bacterial promoter. This line failed to gain a qualified majority in the European Commission's Article 21 Committee. Competent authorities voted against or abstained for various reasons, including the risk of anti-biotic tolerance spreading in bacteria in the rumen of cattle, a possibility that Ciba had not considered adequately.

These cases show that the competent authorities take hazards seriously but vary in their assessment of the risk. Is it possible to quantify the probability of a hazard happening; to quantify the risk to agricultural systems, the general environment and society as a whole? With the controversy surrounding bovine spongiform encephalopathy (BSE) buzzing in our heads, it would be a brave regulator who did not examine any hazard, particularly those declared remote (which usually means unknown).

What are the hazards?

Of the ten or more potential hazards relating to the introduction of GMOs, the obvious agricultural and environmental ones are the spread of the transgenic plant, and the spread of the target transgene through hybridization. In this article, I will focus on recently published results that relate to these two hazards. Two other biological ones are the spread of associated transgenes (as in Ciba's maize mentioned above) and toxicity. For the latter there is already a cautionary tale, involving a lack of sufficient knowledge of food allergies. The development of soy bean containing a gene from Brazil nuts had to be abandoned at a late stage³.

Transgenic plants may also accelerate the evolution of various resistant pests⁴. In addition, there are social, economic and legal hazards⁵ such as the use of a multiplicity of constructs for the same product⁶, conflicts of interest⁷, legal liability⁸, effects on the diversity of crops, effects on farming practices and problems from international trade⁹. The present regulatory systems only address the safety of biological effects, and there is no official standing forum for discussing the other problems⁵. Some of these problems are common to agriculture in general but are more acute for GMOs.

How do we quantify the risks?

The natural way to quantify the agricultural and ecological risks is to do field trials and to consult the literature. But small-scale field trials are normally so constrained as to give little information on hazards, and frequently are not designed to allow sound quantitative comparisons⁹. A recent claim¹⁰ that 91 per cent of trials have had minimal risk, and the remaining ones a low one, depends on classifying the risks (a prejudgment) rather than on the experimental results, and on combining probabilities in a dubious way¹¹.

As an example of the problems involved in quantifying risks, I will describe the situation for oil-seed rape (canola), one of the commonest plants in European trials of transgenic plants. Surveys of the literature accompanying proposals have claimed that there is effectively no risk of hybridization with other species, and that pollen spread to other cultivars will be minimal. Experiments have now shown that there can be appreciable and effective hybridization with *Brassica campestris*¹², the wild and weedy form of *B. rapa* (turnip, turnip-rape and some American canola), and with hoary mustard *Hirschfeldia incana*¹³, with effective gene flow from crop to weed. The hybrids are fertile despite large differences in chromosome number. In addition, studies of pollen flow show that experimental design can lead to order of magnitude discrepancies¹⁴ in the prediction of large-scale (kilometres) dispersal; well designed trials show that significant quantities of pollen travel long distances¹⁵. The mathematics of wind dispersal may be consistent with scale-free dispersal, i.e., dispersal to any distance¹⁶. Altogether, the literature and some trials have been misleading.

Does oil-seed rape become naturalized, does it produce established, self-perpetuating, populations? It is now one of the most conspicuous road-side plants in Britain. One study¹⁷ around the M25 (the London orbital motorway) found that the populations were transient, as stated by the literature on these species. But surrounding fields in Scotland, at least, there are persistent populations¹⁸. Despite these demonstrations that much of the biology of *B. napus* had been misdescribed, the earlier risk assessments have not been revisited and revised.

Can we predict? What are the concerns?

Well-designed experiments could give reliable information on a range of characteristics such as seed production, growth rate and survivorship at all stages of the life cycle⁹? These could be related to the fitness of feral crops and hybrids⁹. The major environmental and agricultural concern is of producing an intractable problem of invasiveness or weediness. In Europe there have been few such cases (an example is the spread of the ornamental shrub *Rhododendron* in Britain⁷) but there are many major problems in other parts of the world⁷. It is commonly thought, and supported by the practice of biological control, that many plants that are a pest as

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[Continued

invaders, but not as natives, have lost their herbivores and pathogens in transit. Transgenics that are tolerant or resistant to pests are being produced in numbers and so, by analogy, a few may well become feral pests. The situation might be similar for other novel constructs.

Two points are well established. The first is that although relatively few new feral plants become problems, perhaps about 1 per cent (Ref. 7), almost all crops occur as transient feral individuals. The other is that most measured characteristics fail to predict weediness or invasiveness⁷. We have to use unreliable tools, weak statistical relationships, to predict rare major events with long-term consequences.

The analogy of transgenic plants with introduced invaders is often challenged because the introduction of a gene is said to make the plant less fit. Here I will just add that the intention of crop breeders is to produce novel plants, and that plants with novel genes will sometimes be fitter than their parents¹⁹, or may evolve to normal or superior fitness²⁰. They might also give rise to new agricultural practices. Plants differing by rather few genes can differ markedly in invasiveness⁷. Familiarity is not a defence against environmental problems, still less against problems of toxicity, or social or economic woes.

So there is a need for better experiments¹⁹, for regulators to be more critical of experimental designs and results, and for the different risks to be brought together for consideration. The costs, which are not negligible, should be regarded as an insurance against the types of disaster that have often followed invasions⁷. These costs have been, and will continue to be, borne by regulatory agencies and industry rather than research councils. They will do so in the interests of safety and consumer concern. Without these costs, many of the benefits of biotechnology could be lost.

ACKNOWLEDGEMENTS

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Review of *Virus-resistant plants: potential ecological impact*, edited by M Tepfer and E Balázs, published in *New Phytologist*

“Only the foolhardy will have firm views on the likely outcome of the introduction of virus-resistant transgenes into agriculture” say Gibbs, Armstrong, Weiller and Gibbs in the first chapter. Virus diseases of plants cause serious losses all over the world, so it is not surprising that transgenic virus resistant plants are, or about to be, in commercial use in many places including China, India and the US, sometimes with multiple resistances.

Transgenic plants expressing virus proteins can be resistant to infection by that virus. That means that one or more virus genes, often coat protein genes, have been incorporated into the plant’s genome. Virus resistance can also be achieved by incorporating benign satellite RNAs. Will recombination and transcapsidation produce undesirable ecological effects? The principal impacts of concern are altered host ranges, altered symptoms, synergistic effects between different viruses, altered modes of transmission. Synergism, where unrelated viruses interact to increase the titre of one or both, is a particular case of the worry that transgenes may produce a favourable environment for change. Altered host ranges includes spreading to related (wild or cultivated) species.

This book “evolved from” a conference in April 1997 (in Hungary) organised by the Directorate for Agriculture of OECD. There are 15 chapters by 47 authors from 10 countries, so it is truly international. The chapters are not numbered in the text, though they are in the contents list, and the indexes are only of plants and viruses, not of topics or authors. All that makes cross-referencing difficult, but a systematic summary in the last chapter by the two editors is helpful. Far more of the book is concerned with the molecular biology of virus resistance than with directly assessing the potential impact, let alone the ecological impact promised in the title.

To what extent are there likely to be real risks from virus resistant plants? The conference agreed that these should be assessed against the risks that occur naturally, and recombination and transcapsidation do. Very little is known about the frequency of either and still less about the extent to which these processes will be changed in transgenics. There will be lots of optimistic risk assessments with the standard line “There is no evidence that . . .”. With commercial lines in places where risk assessments are not taken seriously, we could soon have real evidence if it is looked for and reported. Monitoring is expensive, discouraging reports are discouraged, as we know only too well from BSE.

Still, there are many indicators here that transgenic virus resistant plants may well enhance the natural risk producing processes. “Three of seven recombinant [with a transgene] cause symptoms on cowpeas that were distinct” (Allison, Greene & Schneider). “Transgenic plants expressing viral sequences create a favourable environment of recombination between viral sequences” and “there is a high selection pressure for recombination in transgenic plants” (Jakab, Vaistij, Droz & Malnoe). “In some cases these risks [from synergism] are much higher than would occur if pathogen-derived resistance was used instead” (Palukaitis & Kaplan). And so on.

Despite the lack of information on rates, sequencing has shown that virus evolution has been polyphyletic and reticulate, dominated by recombination. Processes important in evolution, acting slowly, could become much faster in transgenic plants, and there is much opportunity for real ecological innovation. What I doubt is whether, world wide, we have either the inclination or means to anticipate it. But this book does at least show that informative experiments are possible, that risk assessment is much trickier here than with other transgenic constructs, and that there are people at the international level taking the problems seriously.

Examination of witness

PROFESSOR MARK WILLIAMSON, Professor Emeritus of Biology, University of York, called in and examined.

Chairman

486. Good morning, Professor Williamson, and welcome to the Sub-Committee. Thank you very much indeed for having agreed to come and give evidence to us in our enquiry into the regulation of genetic

modification in agriculture. I hope you will, with your huge experience, be able to illuminate some of the tricky environmental issues which litter this subject. You very kindly sent us some extracts from your published work to help us and from them we have drawn some of the questions which we wish to put to

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PROFESSOR MARK WILLIAMSON

[Continued]

[Chairman Contd]

you. However, I would like to raise something that came out of one of the papers. You referred to the instance of the Texas male-sterile cytoplasm in the United States which eventually produced a catastrophe in the crop when it succumbed to fungal disease and was virtually destroyed. You described it in a chapter of the book you sent us as being a genetic modification of corn and we mistakenly assumed that this meant genetically modified by modern methods. We have been subsequently corrected by MAFF that this was not the case and that we had misinterpreted it and, in fact, you meant genetic modification under traditional breeding methods. Could I ask you to comment on that and confirm our new understanding?

(Professor Williamson) I apologise for that. I did use the words "genetic modification" in the book. It comes from my view that one should really be talking about genetic engineering rather than genetic modification but I do understand that genetic modification is the official term and I should not have used it here. This was a natural recombinant gene not caused by the techniques listed in the Directive. This is a single gene on the mitochondria of the corn which makes a particular protein which fits into the membrane of the mitochondria and the fungus produces a toxin that targets this particular protein. It is not genetic modification in the sense in which we are using it here.

487. Fine, but you accept that that is not evident from the chapter as it is written?

A. Yes.

Lord Gallacher

488. Professor Williamson, a question which the Sub-Committee has not asked so far, because it falls outside the remit of this enquiry, is whether the technology is a desirable technology, whether it is a technology which ought to be exploited? What are your views on this aspect, which is fundamental, I think, to the whole business?

A. I certainly agree it is fundamental. My view is the same view as I have held since I first got involved in this field about 12 years ago, that this is a highly desirable technology. It has produced massive benefits in medicine already. The differences in technology between medicine and agriculture are negligible. Indeed, I would like to see vaccines produced in plants in principle. It is a better place to get vaccines, it seems to me, than from rabbits or horses. So it is a highly desirable technology, but like all technologies, it does have its risks. The other view I formed 12 years ago was that this technology in agriculture would only be acceptable if there were widespread public acceptance. I think that is a difficulty we have got into this year, that some parts of the public are worried about the technology, but the technology as such is certainly desirable.

Lord Wade of Chorlton

489. I have really a series of questions, which lead us to consider how current practice is different, from—I am going to use the words "genetic modification" but you would say "genetic engineering".

A. I appreciate "genetic modification" is the official term.

Lord Wade of Chorlton

490. Are GMHT (genetically modified herbicide tolerant) and GMPT (genetically modified pest resistant) plants any more or less likely to harm the environment than current practice in commercial agriculture?

A. This is a fairly complex question. I think as far as herbicide tolerants are concerned, the harm might be from the way that herbicides are used. Herbicides, of course, are already used very widely and I do not see in principle any particular reason why herbicide tolerant should be more or less. There is another underlying worry, that the herbicide tolerant gene put in might have some other unexpected result, in which case you might get something new, but nothing like that has been found so far. I think with pest resistant plants we are in a different situation. I think putting pest resistance into the plants does produce new problems, particularly in the evolution of pest resistance.

491. Going on from there, when you look at the two systems of genetic change, the GM system and the conventional system. Do you think that a similar system of approval is correct in both cases, and again in the light of your comments about the adjusted maize, where clearly something went wrong, even though it was not genetically modified in the sense that is modernly now understood? So do you believe as a result of that that we need better monitoring and a better approval system to look at both systems?

A. I think it would be desirable to have both elements but agriculture is an enormous business. It is a question of how much we can do. One thing that is in the Directive which has never been acted upon is the question of cell-cell hybrids. It is listed as a technique but the committees never ask for evidence on this and never consider it, I think because it is too weak. You certainly should compare genetically modified plants with conventional plants. In the book review I sent to you on viruses, the people writing that book said one must compare what happens in genetically modified plants with viruses in them with what happens in ordinary plants with viruses in them, and that is perfectly correct. The thing about genetic modification in the sense in which we are using it here is that one might possibly—I do not think we have got there yet—get some really novel plants which might produce some really novel problems. So one has to keep a lookout to see if there are novel problems coming up. So far they are modifications of the sort of problems we have been dealing with before, and possibly in the case of pest resistance rather more serious than we have dealt with before but not qualitatively different.

492. So picking up what you have said so far, would it be your view that the main purpose of regulation, unless you have equal regulatory systems for both conventional and genetically modified, which you are saying would be the ideal but is now probably

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PROFESSOR MARK WILLIAMSON

[Continued]

[Lord Wade of Chorlton *Contd*]

beyond practical possibility—is to satisfy the consumer that products were safe rather than actually to look at the basic safety of the products? Would that be true?

A. I do not think you can satisfy consumers that things are safe without looking at the basic safety, but I do agree that the primary reason for doing all this monitoring is, indeed, to keep the consumer happy, and we seem this year to have failed to do so.

Lord Grantchester

493. Would it be fair to say that what we should be looking at is not only the technique but the product? You were talking about genetically modified and conventional systems, but should you look at the new product and analyse the product and monitor it rather than the technique?

A. Certainly from the scientific point of view one should be looking at the product and that is what we have always said on the Committee, that the risks of environmental damage will come from the nature of the product and not from the nature of the method. I do not think there is any doubt that some of the consumer groups are concerned about the method and, therefore, we have to reassure them about the method, and the method does produce sometimes some side-effects. The problem with the Novartis corn is not the pesticide resistant gene so much as the other genes it brought in with it. That is not part of the product but it is part of the method.

Lord Wade of Chorlton

494. What do you believe would be the likely impact of gene technology on the natural environment in the United Kingdom and are the environmental benefits of no-till agriculture likely to be of much benefit in the United Kingdom? We have heard evidence from America that American farmers see that system as a tremendous advantage to their production methods.

A. My Lord Chairman, Lord Wade knows far more about British agriculture than I do but I asked around about no-till agriculture. It has been used a little bit in my part of Yorkshire. Farmers did not find it awfully helpful. They said you still had to use herbicides and the result of no-till was that you were liable to get rather compacted soil and they did not find it was a good idea. So I do not really have views worth reporting on no-till agriculture.

On the question of the likely impact of gene technology on the natural environment, the likely impact is small to zero, but the problem with its likelihood is that there is a small likelihood of getting a serious effect and that is the difficulty. I like to compare the release of genetically modified plants with the introduction of invasive introduced plants. I know the industry does not like this, they say we are working with familiar things, but it seems to me the construct is novel and it might behave like an introduced plant. If you take something like the rhododendron that you see all over the place, that appeared to be perfectly harmless for many years and

yet now is a major pest in woodlands in the West part of England and in Wales, though not in Yorkshire. I think we might get effects like that, where you get rather intractable problems from either the escaped plant or the escaped gene, but the likelihood of that is fairly small, particularly in the United Kingdom. Worldwide I think the likelihood of getting a nasty effect somewhere is rather larger, and probably, looking at these problems in general, one is more likely to get it in the tropics than in the temperate zone, but those are very broad generalisations. I think my middle prediction is small to zero effect on the environment in the United Kingdom.

495. The evidence we have heard from those who are concerned about genetic modification technology is that we could have some great disaster down the road. It might be a very long time off or it could be a short time but it could really have very serious implications for the environment and people.

A. Yes, this is quite possible.

496. How do you respond to that?

A. Yes, we certainly could have such a disaster and it can come out of the blue. If I can take an American disaster, the thing called the zebra mussel which got into the North American system about ten years ago through the Great Lakes and has now gone all the way through the Mississippi Basin, so that it covers most of the central part of North America. That is a disaster for all sorts of people, waterworks and so on, it smothers surfaces. And yet this is a little mollusc that we have had in this country since early in the nineteenth century and causes us no trouble at all. So it is very difficult to predict. Here we have a thing which had invaded Western Europe from Eastern Europe in the nineteenth century without causing trouble, invades North America in the late twentieth century and causes immense problems, and having caused the problem, at the moment there is no cure known. So it is certainly possible that we might have a major environmental problem from this technique. My view is that it is not very likely but it is not impossible.

497. Coming back to your earlier answer to Lord Gallacher's question, where you said you believe the technology to be right and that it is going to bring greater benefits than disasters, would you say that the potential for such disasters could be very much reduced by now looking at further regulatory systems and monitoring systems or do you think that it is a risk that is always going to be there, but on balance that risk is worthwhile?

A. I would say both, if I may. I think the risk will always be there and the monitoring system may well fail to pick it up. On the other hand, you have much more chance of picking it up if you have a proper monitoring system. So we certainly ought to have a good monitoring system, but that comes later in the questions. That is a very difficult thing to do and, as you will see when I come to answer the questions on that, I am uncertain as to how we should do it best, but we should certainly try. We could probably try doing it in several ways and see what the results are.

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[Continued]

[Lord Wade of Chorlton *Contd*]

498. Even with the risk you would still like to do it?

A. Yes, I think so. It depends what sort of products you are thinking of. I am particularly thinking of biomedical benefits from crop modification, things like vaccines and antibodies and so on, because I think this will be a way of getting new and different medical products cheaply, conveniently and, for some people, more acceptably. I think it is a pity that the industry has started with something which only seems to have served the industry, a form of herbicide resistance. It started off on the wrong foot and, to that extent, put it back somewhat unnecessarily early, and it is a pity they did not start with something else. I cannot understand why they started with it.

Chairman

499. Do you think that organic farming and genetic modification are compatible with each other, having genetically modified crops and organic crops living side by side, and could genetic modification be of value to organic farmers?

A. The difficulty with organic farmers is that they have very strict definitions of what they mean by "organic". Personally I would very much like a more sustainable sort of agriculture, an agriculture with fewer inputs of pesticides and fertilisers and all these sorts of things, which is the way organic farming is going. But one of my colleagues was told the other day, for instance, that grapes with seeds in them are natural but seedless grapes are unnatural, and I think once you get into that sort of "angels on a pin" argument, I am not happy with it. As I understand it, the organic farming movement has declared that genetic modification is not acceptable to organic farmers and I think that is unfortunate. I do not see any way in which I am going to change their mind. What I would say is that genetic modification is compatible with sustainable lower input farming, and to that extent it is a thing which I would hope the organic community would eventually come round to welcoming, in some forms at least. But I do not see any prospect of their doing it at the moment.

500. As I understand it, the Bt bacterium is used as a spray in organic farming and no fuss is made about that, but a very great deal of fuss is made when it is introduced as pest resistance into crops. Does that not seem a bit illogical?

A. No, not illogical at all. The thing is, if you spray Bt it has a very short life in the field, it breaks down rapidly. Again when I first came into this ten years ago or so, when we first had Bt constructs to talk about, everybody said, "There is no evidence that any insect will develop resistance to Bt. It is a marvellous pesticide. All other pesticides they develop resistance to, but not Bt. We have been spraying it and no resistance has developed." If you put Bt into a plant and keep it there permanently so that it does not decay, you can, in fact, develop Bt resistance quite rapidly, within a few generations. So I think having Bt in the plant really is a very different scene and one which does need careful management and careful control.

Baroness Young of Old Scone

501. Could I ask a supplementary, Professor Williamson? You have described one environmental impact and assessed the risk of that, and that is what I would call the rampant species, the "thug" species such as rhododendron. Some commentators have suggested that there might be other impacts, particularly on beneficial insects and also perhaps with broader land use change. I wonder if I could ask for your comments on that?

A. Certainly on beneficial insects. One worry that has emerged about Bt in plants—and they actually tried it with the Novartis corn borer—is that if you then feed that corn to herbivorous insects and then feed those herbivorous insects to predatory insects, the predatory insects may show an effect. The same has been shown in Scotland, I think, with a different insecticide in potatoes, where you have ladybirds affected by the aphids. So I think knock-on effects through the food chain to beneficial insects are a possibility and it is one of the things that should be monitored for. Certainly we do not want to decrease the number of beneficial insects if we can possibly help it but modern agriculture does decrease beneficial insects anyhow. When you spray a broad spectrum of insecticides you lose your beneficial insects along with your undesirable insects.

502. The other question was on broader land use change.

A. I am sure that the development of genetic modification, if it becomes accepted in the European Union, will lead to land use changes, but I would say there all farming changes lead to land use changes. How long ago was it before we did not have yellow fields all over the United Kingdom? Now if you look out of your window you see yellow patches everywhere because oil-seed rape has become very common, and this is a land use change of sorts. Now we are getting more blue fields. I think agriculture is now using science to such an extent that it is going to change irrespective of genetic modification and there will be land use changes. I would not have said that there would be greater land use changes from genetic modification than otherwise, but I would say there will be land use changes from genetic modification. Again it is a question of coming back to the Government to say whether these land use changes are politically acceptable.

Lord Jopling

503. Professor, may I follow up an answer you gave to Lord Wade a few moments ago when you talked about a situation, during the process of genetic modification, where you used the phrase, or something like it, of "other genes creeping in".

A. That is right.

504. Could you explain to a group of non-scientists exactly what that means and how it can happen, with three particular questions in mind: is it always accidental or do scientists realise that other genes may creep into the process of genetic

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[Lord Jopling *Contd*]

modification and say, "Well, so be it. It doesn't much matter,"; then when other genes creep in, to what extent is it easily detectable, or is it impossible to detect until the effect on the organism of those other genes emerge; and the third side of it is, is it avoidable to have other genes creeping in in the process of genetic modification?

A. They are quite deep questions. On the first one, whether it is accidental, the answer is no, it is done on purpose. They put these genes in in order to be able to make the construct and find out what they have made. Perhaps I could compare it with scaffolding on a building. It is difficult to build a building without scaffolding or a high crane or something, but when you have finished the building you take it away. In the genetic constructs that we have coming on the market at the moment, the scaffolding has not been taken away, it has been left in. So it is there deliberately and the people doing it were of the opinion that it was of no great consequence and I think they were surprised when European Committees said they did think it was of some appreciable consequence.

The second question you asked was whether it is detectable. I do not think I am the right man to ask this because it is microbiology but I would say it probably in all cases now is detectable, at a price. With DNA techniques you can detect practically anything in a nucleus if you are prepared to put enough money into developing appropriate probes and that sort of thing. It is not the sort of thing you are going to be able to do on the back of a tractor on a farm. It would be an expensive process as it stands at the moment but it could be done.

The third question you asked is whether it is avoidable, and I think the answer to that is, yes, it is, but you have at the moment to think about it when you start the process. When you first start to put a gene into a plant and you put it into the plasmid to be carried into the plant, you put in with the gene you are going to use—the Bt gene or whatever it is—an antibiotic gene or a herbicide gene or some other thing you are going to use, to allow you to select your right lines, you can flank that gene with what you might call weak links, things which are attackable later on. So you could make your original construct in such a way that you could effectively get out the scaffolding later on. But people are not doing that yet and getting it out now in the constructs that we have in the market would be very difficult for companies. I doubt it would be impossible but it would certainly delay them five years or more, I would imagine, while they went back and redid it from scratch. Having done it once they would know where they were going a bit faster but it would still take several years of breeding to succeed.

Chairman] You will be able to see that, Lord Jopling, in detail and carry the discussion further when we visit the John Innes Centre in Norwich tomorrow.

Baroness Young of Old Scone

505. Could we cast our minds forward a bit. You have already touched on the issue of whether it was the wisest thing to start with a set of objectives that appear not to have as many public benefits as might

be the case with other modifications. The concentration so far has been on herbicide tolerant and pest resistant crops. Are there other modifications that you think could be of less or different environmental concern, and the three groups I would like you to think about are the groups that allow crops to tolerate things that they otherwise do not: firstly, fungus resistance, salt and frost tolerance; secondly, the manipulation of nutritional property and quality standard, and thirdly, pharmaceutical production?

A. In your first category you put in fungus resistance, which I would regard as just another kind of pest resistance, but the other two you put in that category, the salt and frost tolerant, are, I think, developments which would need very careful ecological monitoring. At the moment, for instance, with maize, most maize grown in the United Kingdom at its northern limit needs a good summer to do well and that sort of thing and we are unlikely to get any escapes. I do not think you get many volunteers. There have been a couple of records of casual maize but not very many. If we got to a much more cold tolerant maize, I think we would get many more, so there will be a greater prospect of escape from modified maize crops if they were cold tolerant. Similarly with salt tolerant plants, you might well get some occurring in salty habitats, which include, of course, the verges of motorways, and you might get a nasty problem cropping up simply because of the salt tolerance. So I think salt and frost tolerance are likely to produce larger problems than herbicide tolerance certainly, problems of a different sort but maybe of the same problematical nature as pesticide tolerance.

In your second category on nutritional property, maybe you are thinking of Flavoursaver tomatoes and this sort of crop. I think most nutritional changes which occur in the edible parts of plants—leaves and roots and things—are not likely to lead to environmental problems, I think less likely so than other ones. But nutritional problems in seeds might. One of the earlier ones we had along was when they wanted to put a Brazil nut protein into oil-seed rape seeds. I do not think that actually developed anywhere but that could possibly be a problem. With oil-seed rape, you see it along roadsides, it produces masses of seeds into roadsides and yet hardly ever forms permanent populations. I think there are a few places where it might. This appears to be because mice and snails and I do not know what—fungi maybe—come and attack the seeds. If you change the chemical composition of the seed it might be that these things that eat it will no longer eat it, in which case you might then get a worse problem from oil-seed rape. So I do think we would need with those sorts of properties to try and develop experiments on seed survival, if possible, to see if we were likely to have problems with that.

The third one is a total black box, pharmaceutical products, but it is the same issue. A pharmaceutical product, as I said earlier, I think would be desirable but might nevertheless have ecological side-effects, and again because it might affect the population dynamics of the plant. The same would apply for plants producing plastics, which has been a suggestion.

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[Baroness Young of Old Scone *Contd*]

You would have a totally new chemical inside the plant which the herbivores of that plant had never met before and you do not know what effect that would have on the herbivores. The likely answer is it will have no effect at all but it might cause some indigestion so they stopped eating it or might even kill them. In which case you then get a really serious problem from feral crops, but again what I think you should do is experiment and find out.

Lord Rathcavan

506. Professor Williamson, you have made it known that you consider risk assessment based on hypothetical questions and small-scale trials to be effectively useless. What alternatives might there be?

A. If I could come back to your question, I was not actually referring to hypothetical questions. It will come in when we get to the end of the questions. It is the questions that DG XI ask us to ask which strike me as useless, because they are too qualitative. I think one should be asking quantitative questions. Small-scale trials, when I say they are useless, this is in relation to ecological problems. Small-scale trials are certainly useful for telling us whether the plant is behaving in the way it should behave as a physiological plant, whether it is growing properly and that sort of thing, but it does not usually tell us anything at all about the likely ecological behaviour. The question, I think, should be very much sharply focused on what possible ecological risks there are. I will be coming back to this, but I think one of the problems is that all the things which you might think would predict whether a plant will be invasive—the rate of reproduction, the number of seeds produced and that sort of thing—are on the whole rather bad predictors. So it is difficult to suggest to companies that they should put a lot of money into measuring things quantitatively, which may in the end be of no great use. Nevertheless, I think one should do some measurements of this sort. They should be quantitative measurements. We do want to know about the seed production of these modified plants; we do want to know about seed survival of these plants. It would be a better thing to have some idea about whether the dispersion patterns are different and that sort of thing. Primarily it is the immediate factors affecting the fitness of the feral plant you need to ask questions about and which the DG XI questions signally fail to ask about.

507. Would you regard invasive properties and the unknown outcomes in this field as being the most serious threat to identify?

A. From the ecological point of view it is the threat of invasion either by the plant itself or by the genes from the plant which have an immediate effect. You can only get secondary effects building up on the back of that, as we were talking about with predators. Certainly with virus resistant plants there are very considerable worries that they might, out in the wild, form new virus diseases. But all these are, in the way I use it, new invasions. So yes, I would say in general we are worried about biological material invading

ecosystems in a novel way and are attempting to get a handle on how likely it is. I do think, however well you design your question and run your small-scale experiment, you are not really going to get very useful answers out of small-scale trials, however well tuned your questions are. We are going to have to go to larger-scale trials and monitoring. Perhaps I could use an analogy here with drugs in medicine. With medicine you start off with a small-scale trial to see if a drug does what you want it to do and then you go to larger-scale trials. It is usually in the larger-scale trials that you will find the nasty effects that you do not want to find, and the phase three trials is where you may lose your drive because of unacceptable effects, and I think this may happen with some of these modified plants. It is at the large scale where you are likely to have nasty effects which have to be cleaned up rapidly, but the probability of this is still small.

Chairman

508. So large-scale trials means thousands of acres, does it?

A. Yes, commercial size.

509. It means commercial exploitation? You could not have such trials without commercial exploitation?

A. I think it would have to be done commercially and involve a lot of commercial farmers before you got to that scale. But it could still be that you might have a provisional licence to the farmers, that you could try growing this crop for such-and-such a period and see what effects there are. Then if you find no effects, you could say, "Okay, we will put it out for full-scale release." That will not, of course, necessarily protect you. A lot of these effects come on rather slowly and you may get a nasty surprise ten or 20 years down the line.

510. And these conditions would be covered under a monitoring system?

A. Yes, you would have to do the monitoring of the crops.

Baroness Young of Old Scone

511. Could I follow this up. You said as a result of large-scale commercial trialling, second-stage trialling, as it were, if adverse effects were detected there would be a need to clean up rapidly. How real do you think the possibility of a clean-up is? We have had evidence from other people who have said that once the genie is out of the bottle it is out and you are not able to get it back in again.

A. I think it is possible. It is difficult with plants. I could send you perhaps a manuscript I have on eradication of environmental problems. It is certainly true that if it is a large organism occurring in a well-defined area such as an island, it is much easier to eradicate it and most successful eradications have been done in this way, but not all of them. There is a famous case where African mosquitoes were eradicated in Brazil after they had covered a large portion of Brazil. That was an enormous exercise in

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[Baroness Young of Old Scone *Contd*]

the 1930s. So I think eradication of a feral crop plant would be possible but it would be very expensive.

Lord Grantchester

512. Could I expand this question of risk assessment. In your paper you ask a question yourself: "Is it possible to quantify the probability of a hazard happening; to quantify the risk to agricultural systems, the general environment and society a whole?" Could I ask you to answer your own question?

A. Yes. I think the paper singularly fails to answer the question at the end but papers often do that. I think at the moment one of the worries I have with the ACRE system is where we go through—I say "we"; I was with ACRE, I am no longer there—but ACRE goes through what it calls a risk assessment. Engineering friends who do real risk assessments of whether a chemical plant will go bang or a building fall down say these are not really risk assessments because they are not properly quantitative. At the moment it is very difficult to get enough good quantitative information of the right sort to do what you can really call a risk assessment, but it is possible to make some progress if you try a little harder than some people have. I would not go further than that. I think we can do better but I do not think we can do well.

Lord Willoughby de Broke

513. Professor Williamson, we touched on monitoring earlier on and I know you chaired the ACRE sub-committee on monitoring. Can you explain what monitoring could achieve, how it could be done, by whom and for what purpose?

A. ACRE produced a series of reports that look like this. I do not know if you have had the privilege of seeing them. I put "privilege" in inverted commas, I think; they are extraordinarily dull documents, but they do say, for example, "Guidance for experimental releases". They were concerned with small-scale monitoring, I think, in all those documents and we are now talking about both small-scale monitoring and large-scale monitoring. But I think broadly speaking we monitor for two reasons. One is compliance, that is to say if the product is let out under certain conditions, limited trials of some sort, and even a commercial trial can be under clearly defined conditions, then you monitor to see if the companies are obeying these conditions. The second reason we monitor is to see if there are unexpected effects. So you go out and say, "We don't expect any hard effect of this sort but there might be so we will go out in the areas surrounding the field and see what we can find", or "we will rely on an army of reporters who will be around the field and see what they can find." Again these are normal practices in medical trials. In medical trials and, as you have probably heard, in agricultural trials, on compliance, although companies tell us they are all splendid, some companies sometimes are not as splendid as they should be and we find that they do slip up and fail to adhere to the conditions. So monitoring even of small-scale trials does show up

lack of compliance. On the small-scale trials you are not going to show up, as I said before, much of ecological interest; it would be of physiological interest. You need a larger scale to get to where you can monitor for ecological effects of interest. Does that help?

514. Yes. Could I follow that up by asking if you are aware of the monitoring of environmental impact in any other countries and whether it is effective?

A. I think the answer is I am not really in the field enough. I was involved with OECD about ten years ago and then I got to know what was happening in most OECD countries. I suspect where this technique is being used most rapidly is places like China, India and Israel, which are not even OECD countries. I anticipated your question and on Monday attempted to surf the web and looked for sites which are run by the United States Department of Agriculture to see what they said about monitoring and I failed to find anything at all. So I sent an e-mail but the problem with sending e-mails to America is it is rather late in our day and early in their day when you send them. I sent an e-mail on Monday to say could they tell me more about monitoring and by the time I left on Monday I did not have an answer. I was not in the Department on Tuesday, so I have to say except for monitoring for pesticide resistance round some of the crops which we do know is going on in America, I do not know of any monitoring. I would be surprised if in America there was much commercial size monitoring because most of the releases are done under a notification and not under a permit and that in itself implies that they do not think there is any need to monitor. So I think you will find that monitoring at the moment is likely to be rather a European phenomenon, but certainly not entirely so. I am going out to Australia maybe in the New Year and I am going to talk to people out there. I am told that genetic modification is a hot potato and I must be careful about what I say, so I may discover later on what the Australians are doing about monitoring but I am afraid I do not know at the moment.

515. Thank you very much for taking so much trouble.

A. It is no trouble to read it up. It is more trouble to find out if it is going to give you any useful information.

Chairman

516. Nevertheless, in your published work you refer to the desirability, in your view, of having an international monitoring system. Could you say perhaps what you had in mind?

A. Yes. I came across two analogies with this one. I think the more helpful one is again in the medical field where the World Health Organisation does run an information network; they have a database in Sweden, I believe it is. I have something from the British Medical Journal of 1997 which describes it, which I can put into your papers if you wish. There you are looking for unusual adverse drug reactions and you get reports in. You can get many reports on adverse

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[Chairman *Contd*]

reactions having taken the drug, but, of course, many of them will not be adverse drug reactions; they will be adverse reactions of some other sort. So you have to sift out your problem. This is a major problem for the World Health Organisation and they have devised computer algorithms to sift through the data coming through. So that sort of system does exist at the United Nations level, and I suspect if one is going to trial internationally it would have to be a United Nations agency of some sort which did it. That is an information system and an international monitoring system. You used the word "separate" there. I did not have strong views on whether it should be separate or combined, but I do think if you set up a reporting network of some sort in a sense it is doing some of the monitoring for you. Again, if we do the large scale trials in this country, although we might require the companies to do some direct monitoring, I think we will be relying on the statutory agencies and on the agricultural community and on amateur naturalists and all sorts of people to form a reporting network if it is going to be effective. The thing about commercial trials is that it has to be big if you are going to have a probability of picking up the effect, and that means you will have to have an awful lot of people out there looking at the effect. They have to be told that people would like to know about these effects, they have to be told how to report them if they find them. I think this comes back to Lady Young's empire.

Baroness Young of Old Scone

517. I was wondering if we could get Professor Williamson to give us a flavour of the sorts of things he would see this monitoring network gathering data on?

A. If we are dealing with crop plants, the primary thing we want to know is whether the plant itself is forming self-sustaining populations outside agriculture. We also want to know for those which cross-breed with plants which are there already, whether they are getting interesting new hybrids. At the moment, the compliance monitoring is done by the Health and Safety Executive's inspectors who are certainly not expert botanists. They can see if the crop has been planted in the wrong place but I think they will be hard-pushed to distinguish oil-seed rape from wild turnip; it is not that easy. Who you need to do this are expert botanists, either professional botanists employed by English Nature, or amateur botanists in the Botanical Society of the British Isles. I suppose the analogy, and again you might be looking for effects this way, are with the bird surveys. I think the best surveys we have had in this country have been surveys of bird populations, which have certainly shown the massive environmental effects of agriculture, the massive decline in bird populations which you have probably all read about in the papers. These are done under contract from the JNCC, I believe, by the British Trust for Ornithology who are professionals who organise amateurs to count the birds. You have a whole army of amateurs out there counting birds, reporting back. Of course there is the recording and entering of it into data bases and analysing them, so it

does cost an appreciable sum of money. You could say in this context it would be up to the companies to fund English Nature to fund the British Trust for Ornithology, though I have worries about that too with the corruption you get from contracts. But I do think it is going to have to be done by bringing in a large number of people. We might require companies to do something directly as well.

Lord Wade of Chorlton

518. You were referring earlier to therapeutic products and there is quite clearly a system laid down for them, with the various stages, number of patients to be treated and the number of volunteers to be found, all laid out in the legislation. The companies which produce the products are aware of the potential cost of the process and it is built into their costings and they can see the benefits coming out at the end of the day. Would you say that that basic principle is one which could be adopted for genetically modified crops and it could be laid down exactly what size of acreage, for how long and what issues should be monitored, so it is part of the company's overall cost to get that product into the market place? On the other hand, the pharmaceutical industry can carry high costs but possibly food companies could not, so in trying to give more confidence to consumers would it hamper it rather than support the product?

A. There are a lot of threads there. I think the answer is yes, the companies should allow for the cost. Whenever I talk to companies about this, they have always said that what they would like is firm and clear regulations so they can see what the cost is going to be and allow for it, or indeed, as you say, decide whether it is more expensive than they care for. I get the impression, reading the financial papers casually—I cannot say I read them at all intensively—that some of these companies are expecting to make a great deal of money out of this and therefore I would have thought they could take on the costs of some of these things at the same time. But it is a question of doing the calculation and seeing what the cost comes out to be. The problem is doing the regulation and saying what it is. You are talking about what the acreage should be and who should do the monitoring and the trouble is we are still very much on a case by case basis. With the Novartis insecticide resistant corn, the concern that came up was that we might get antibiotic resistance developing inside the guts of cows. I do not know if one is going to require the companies to go around and sample the gut contents of a large number of cows. It obviously can be done but it is not what they were geared up to do, they would have to bring in another section of their company or another company altogether. It would be very difficult, I think, to have a regulation which would indicate how many cows and for how long you would have to monitor for this. The company would have done better to have avoided the problem in the first place by excluding the antibiotic gene, as I was explaining to Lord Jopling, but the companies did not think of this when they were starting their development a decade or more ago. Yes, I think the companies should be expected to allow for

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it. I think it is not feasible to be able to give as firm an indication as the companies would like, and I would have thought the answer for the companies would be, as in many cases where you have unknown risks, that you would do it on an insurance basis. The Government of course insures itself and does not take out an insurance policy, smaller companies would inevitably take out an insurance policy for all sorts of risks, larger companies would no doubt have to decide whether they wish to have an insurance company for an unknown expected large thing or whether, being large enough, whatever comes they will be able to weather it.

Lord Grantchester

519. Following on from your point about antibiotics and cows, what I would like to ask you is, is the furthering of antibiotic resistance through genetically modified food a genuine cause for concern? How can the least safe practices be identified and phased out?

A. Is it a genuine cause for concern? It depends on the antibiotic resistance. If you have—and I am sorry if I am going to say things which you know very well already—a bacterium which is resistant to an antibiotic, it does it by having a gene that produces a product that fights the antibiotic in one of a number of ways. Then you can put that gene into a plant as a marker in the development of the plant. The gene will be under the control of a thing called a promoter and promoters are a branch of witchcraft in which I am afraid I am not trained. But I can say there is a difference between promoters which work in bacteria only, which are the sort which a bacterium normally has when it starts off, and promoters which will work in plants only. Most of the promoters which have been used for putting in antibiotic resistance genes in plants, are plant virus promoters, particularly the cauliflower mosaic virus promoter, and these on the whole will only work in plants. There are, of course, other promoters which will generally work in plants but which sometimes work in bacteria, or might even work in mammals, which is why I say it is all witchcraft. The only way to find out whether a promoter will work in a different organism at the moment is to try it. I have been critical of some people who say, “This product is safe because of such-and-such”, before having done an experiment. I think with a bacterial antibiotic resistance gene in a plant under a plant-specific promoter, the concerns are very small indeed. It has got to get out of the plant into a bacterium, lose that promoter, gain another promoter, and then it will start acting. All that is remote, as the industry is likely to say, which means a very small probability. It is not impossible, practically nothing in this field is impossible, but it is very unlikely. The problem with the Novartis product is that they put in a bacterial promoter and that of course, when it gets into the cow’s gut, could well get into a bacterium and start working straight away. That is very much more a cause for concern and that is why the British position on this was that there really was cause for concern and something should be done about it. So, again, it is a

question of a particular case, because with antibiotic resistance there is always some slight cause for concern, usually very slight. In some cases using bacterial promoters is a considerable cause of concern. If I could take another case, where they are putting constructs into insect viruses. There they are putting in promoters which will drive the scorpion toxin gene, and the promoter is one which is new to that virus and new to the insect receiving it. There is a mild concern at the back of my mind that the product there actually could be toxic to some mammals, and that the promoter could conceivably work as a mammal promoter. It does not look like a mammal promoter but as far as I know people have not tried to see whether that new promoter does work in mammals. I think the answer to all these is that we need more focused experiments on the lines of, “Here is a possible risk, what experiment can we do to test it?” In that particular case I think the optimum test is possibly promoting activity in mammal cells, and I do not think they have done it. Did I answer the first part of your question adequately?

520. Perhaps I could interject that the way you have answered so far leads me to believe that the cause for concern to your mind is whether it leads on and out into other species, the environment and so forth?

A. Yes.

521. Rather than the nature of the antibiotic, which would lead me back to say should not the use of the antibiotic itself, such as the use of ampicillin, which is still a useful antibiotic today, should not that be a cause for concern, not the fact it can get into the cow’s gut?

A. Again, we get into one of the detailed arguments about which particular form of ampicillin is used and who uses it. We certainly get these arguments about kanamycin, which of course is the common one, and people say, “Kanamycin is never used at all”, but my medical friends tell me that it is still used but rather rarely, and neomycin, which is used rather more commonly though again not all that frequently. There is another possibility with antibiotic resistance genes. If you have the antibiotic resistance gene under a plant promoter it will be forming, quite rightly, a protein in the plant, the same protein that in the bacterium is used to fend off the antibiotic, and that conceivably could have allergenic or toxic effects, particularly if you get a nasty mixture. One of the undesirable things one can see coming from this technology is that you will get plants with multiple constructs and then they are going to have all sorts of different antibiotic genes all forming small quantities in plants, and maybe this mixture of small quantities of things might turn out to be undesirable. But, again, it is one of these unlikely risks but one which one can consider and do something about. I think it comes to, as you say, how can one identify the least-safe practices and phase them out, and I think this is a very important question. Certainly my plant molecular biology people say that the idea of putting an active bacterial antibiotic into something you are going to feed to cows which are already full of antibiotics for various other reasons, does show a total lack of imagination on the part of the company

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[Lord Grantchester *Contd*]

and they should not have ever started down that road. But, of course, in America, this is a notification procedure and nobody gives a damn. In Europe, where we are much more concerned about these sort of risks, the answer is you could require the company now to take it out and you should perhaps require it under a timescale because, as I said in earlier answers, it will be a slow process for the company now to take these out. They are going to have to go back probably to the cell culture stage to take it out, but it could be done, and you could insist on it being done and you could say, "Okay, we will have a licence for this corn for five years with these things in and meanwhile we are monitoring but after five years all corn grown which is genetically modified must be free of antibiotics." You could have a regulation which said that. It might conceivably improve consumer confidence if you did say that. A lot of these actions will be not so much to counteract the risk as you estimate it, but to improve consumer confidence that you are doing everything possible to avoid risk. Of course, with BSE we do know how very important it is not to underrate any sort of risk if we are going to keep the confidence of consumers.

Chairman

522. It is not, surely, an antibiotic that the corn has in it, it is an antibiotic resistance gene?

A. That is right.

523. There is no actual antibiotic in the corn.

A. Yes, that is right. There are actually two antibiotic resistance genes in it, if I remember correctly, but it is the ampicillin one which is the one which causes concern.

Lord Jopling

524. Professor, as you know the current European regulatory system under Directive 90/220/EEC is being discussed and there is a Commission-proposed series of amendments to it. Will you tell us what you think to be the main faults in both the existing structure and the amendment which is currently being discussed, which I believe the Government think will take two years. I wonder if you could tell us what you believe ought to be amended in those two years?

A. I think the short answer to what is wrong with it, is an awful lot. It seems to me an extraordinarily unhappy document and I would hope that the British would make major changes to it. As a short first step I would take out the whole of annex 2 and annex 3 and start again from scratch. I think you will find annex 2 and annex 3—and annex 3 is the old annex 2—are derived from the Directive as we have got it from 1990, which took a few years of negotiation. I do remember a discussion of this at OECD meetings in the late 1980s when we tried to persuade DG XI that perhaps they might modify, looking at the best set of characters instead of being rather vague, but they were what you might call not receptive and they were not modified. This list of characters which you get in annex 3 comes from the 1985 OECD document, the

thing which used to be called the Blue Book, which may be misleading here in the Houses of Parliament. In an annex to the Blue Book you have got all the characters listed there. I did ask a gentleman from the Health & Safety Executive if he knew how it came about and he said yes, he had chaired the meeting, and they had an evening session where they had a brain-storming session and asked everybody to think of anything they could put down on paper which might possibly be relevant, and they slammed them all down, and we have still got them. I do think in 1998 we should not be using a list devised one evening in 1985, I think we should be doing much better than that. If I might be a little more constructive—that is all rather destructive—I would say that you cannot do a quantitative risk assessment by asking for qualitative information. If I can turn to annex 3 on page 72 of the document I have, Part C, section 2(d) you do actually get a quantitative question on the "rate and level of expression", but I think it is almost the only quantitative question in the whole document. If you go higher up, asking for "the description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed", is just too vague to be helpful for a risk assessment. We do need to know this information somewhere as background information, but what we are trying to do is a risk assessment not getting background information, and I think you cannot do a risk assessment from this document.

525. Would you give us the reference for that second point?

A. That was C 2(a), three sub-sections up from the one I was talking about on page 72.

526. "Description of genetic traits"?

A. Yes, that is what I am talking about as being vague and qualitative. "Stability of the organism", unless you say we want this measured in a particular way, that is the same. Sub-section (e), "activity of the expressed protein(s)", what sort of answer are they expecting here? If you put it out to 15 competent authorities to look at this, are we not going to get 15 different answers? The whole thing I think is far too qualitative and really pays no attention to where we really are in understanding risk assessment. I think the whole field of risk assessment was clarified greatly by a Royal Society report in 1992, from memory, which is now used for health assessments, where they distinguished in the first part of the report in an engineering sense between hazard and risk. A hazard is something which can go wrong, a risk is a probability of it going wrong. I think what we have got in this document is what I would call a hazard assessment. They talk about things which might go wrong, we do not get anywhere near a risk assessment of how likely they are, let alone what sort of action you should take in the light of this probability. I think there is also a third stage which still does not come through in the ACRE and HSE proceedings, which I think is very important in the field we have here. It comes in the back of the Royal Society report and that is the public perception of risk. Again, if I can go to medicine, if we have two risks of low probabilities,

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[Lord Jopling *Contd*]

1:100,000 say, and in medicine this is something you are going to cure, you will say, "I am quite happy to live with that sort of risk, I do not mind it." If you are dealing with food, you may well say, "Despite the fact of it being a very small risk, the after effects are so nasty I do not want to live with it at all." Certainly if we go back to beef, there were some of us in 1988 who said, "Okay, we now know there is a nasty disease coming forward from cows, we have no idea what the probability of ourselves catching it is but we can avoid it by not eating beef, we can eat pork instead." So with food, people are going to insist on a much higher level. The perception of the nastiness of the risk is going to be an important part of the assessment. I think is not at the moment in the ACRE procedures but there have been calls for attention to the social sides of risks and this, I think, is part of that scene.

Baroness Young of Old Scone

527. Can I ask one other question in terms of risk assessment and that is, should we have to take into account the reversibility of any change that is being assessed? You talked earlier about the clean-up as a result of monitoring, should it be part of the risk assessment how permanent the hazard would be, were it to happen?

A. Yes, though it is difficult. One could distinguish. If you are getting a crop going out which might unexpectedly produce allergenic effects, then you can say, "Okay, we are going to be able to get rid of these effects once we discover them just by stopping growing the crop". Okay, but that is not an environmental effect. I think when we get an environmental effect—with allergenicity the crop might turn out to be allergenic to wild mammals of some sort and you might suddenly find all your foxes or sheep were suffering severely from eating casual amounts, either directly or indirectly—you could then say, "Okay, this crop is having an undesirable effect" and call it back. I think if we are talking about invasion either of the feral crop itself or invasion of the gene into the wild relatives, it is very difficult to know in the early stage how recallable it will be. We talked earlier about the difficulty of eradication, but you can eradicate. You were also asking, and I think I did not really complete the answer, about companies being liable for restitution, and I did have an analogy there—a case which came up again on my local friendly computer. In Australia they grow olives, as it has a suitable Mediterranean climate. They find that olives are escaping into the native Australian vegetation and they do not like it, they want to get rid of them, and they find they can control them in the bush. I do not know how they do it but I presume they cut them down and paint them over with a herbicide, that is how you usually control trees you do not want. But they are having continuing problems because the olive farmers do not really care where they dump their surplus olives and they have a lot of olives dumped on the wayside somewhere, and from these they are getting invasion. They are saying they are having no luck in persuading farmers to use more environmentally friendly ways of disposing of their surplus olives. So if you have a crop

that is producing minor environmental problems from escape, then you could insist on certain farming practices and have regulations there, so that the problem was certainly greatly diminished and, with a bit of luck, removed altogether.

Lord Wade of Chorlton

528. If I could follow that? Bearing in mind again what you were saying to us earlier, clearly the possibility of something going wrong through traditionally modified crops is just as great, from what you were saying, as it is with genetically modified crops. With the traditional system we have had all kinds of problems. Since farming began we have had weeds and animals which have gone wrong but we have found solutions to all that.

A. No.

529. Why not? We have, because we have been able to succeed and carry on and increase our production, so we must have found solutions. We are all here! We have not had some disaster which wiped us all out. Is there any reason to believe that something that might go wrong as a result of genetic modification is likely to be any more serious and likely to be unable to be coped with than any other problem that the agricultural industry has solved over the last 2,000 years?

A. Well, yes. There was an earlier House of Lords Select Committee on Science and Technology report, I seem to remember, where I answered pretty much the same question saying that I do not think there will be any new problems, and we had a certain amount of excitement because somehow in the record the word "new" got left out. The problems will be of the same sort that we have got now, but that does not mean that they will not be intractable problems because we do now have intractable problems. In the United Kingdom we are really rather fortunate with most of the problems we have. You can say that oil-seed rape in pea crops and these sorts of things are perfectly tractable problems providing you go to some expense. A recent case where agricultural practices have led to a weed problem is weed beet. Weed beet is a variety that had been formed by agricultural practices in the south of France and the north of Italy and you can indeed control weed beet by controlling it with glyphosate, which is why we thought Monsanto was perhaps not following the best course by developing glyphosate-resistant sugar beet because that would make the weed beet problem less tractable but certainly not intractable. To give you a case which is actually intractable in this country but which you do not observe, there is a disease called pine blister disease, if I remember correctly, which attacks certain conifers and particularly five-needled pines. I do not know, Lord Wade, if you know about pine trees but if you take a pine needle off you will find it has got a sort of a sheaf around the base and the normal pines we get in this country have two needles and there are two-needled pines, three-needled pines and five-needled pines. There are almost no native five-needled pines in Europe, although there are plenty

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[Lord Wade of Chorlton *Contd*]

of them in North America. There is the Weymouth Pine, after Lord Weymouth who introduced it from North America, which looked as though it was going to a very useful forest tree, a good white wood tree. But this is highly susceptible to pine blister disease and no cure has been found for the disease, so the foresters in fact do not plant this pine now, they plant pines which are not susceptible to the disease. So in a sense that solved the problem but you solved it without curing it, you solved it by side-stepping it. In many cases we will be able to side-step problems but there will be other cases where you cannot side-step problems, you will have an intractable one. To think of cases one has seen pictures of, they are usually ones which are tractable because when the thing has been totally lost you can no longer use it and you do not get pictures of it. I have got pictures of Queensland in the 1920s which was completely smothered in prickly pear, and that was at that point a totally intractable problem, and they lost, being Australia, no doubt millions of acres or hectares through it. That was in fact solved by biological control—they managed to find an insect which would eat up the prickly pear.

530. Quite, they found a solution.

A. I see no reason why you should not eventually with some of these genetically modified things come across an intractable problem where you will just abandon doing that type of agriculture in that type of way because the problem is impossible. You will use your land for some other purpose.

531. That is the solution.

A. Yes.

Chairman

532. The starting point for these questions was the EC regulatory system. Did you say all you wanted to say as regards your views on the current regulatory system within the Community?

A. I think, Chairman, saying how it should be done, re-writing annex 2 and annex 3, is not a thing I would either want to try to discuss with the Committee in the time we have available, or that could be written down. I think it is the sort of thing where I would hope that the people who were discussing this document will bring in people who do understand risk assessment and who do understand ecological risks and get in appropriate experts. It will take them, as indeed Lord Jopling was saying, a couple of years I suspect before they come up with a draft. I was just throwing into the ring the suggestion that they are so hopeless, they should start again from scratch on these two annexes, and see if that persuaded them to call in a useful expert committee to thrash out how it should be done.

Lord Gisborough

533. I am not sure you have not answered this just now, but how would you regulate to prevent disasters which may not happen for decades? Do you support a moratorium?

A. Two questions there. Let me start on the first one. How do you regulate to prevent disasters?

Particularly with invasives, the lessons we get from invasive problems are that they are on the whole unpredictable, they come out of the blue. We have talked about the zebra mussel before where, from what we knew, nothing would happen. It can happen quite quickly as it did with the zebra mussel, or they can happen over very many years. The rhododendron was not a problem for decades, even a century, before people started worrying about it, and it is now quite common. Another case of a well-meaning introduction which is now a problem is the muntjac deer—

534. Or the grey squirrel.

A. I have quotations in my book where people say muntjac is an entirely harmless thing, and we had the same arguments about grey squirrels. Mammals are easier to think about. I think we may well get disasters which may not happen for decades and the analogy I would draw your attention to there is earthquakes. Earthquakes are very different from genetically modified plants but they are also large-scale, unpleasant and unpredictable, and the Japanese, as I am sure you know, have put in money—I hate to think how many zeros because the yen has quite a lot to start with—into trying to predict earthquakes. As they discovered in Osaka, all their predictions were a waste of money and they got nowhere with them at all. I think it is now generally agreed amongst earth scientists that earthquakes at the moment and for the foreseeable future will be unpredictable, but that does not mean you do not do anything about them. You certainly have building regulations to ensure in zones where you expect an earthquake sometime, but you do not know when, that buildings will not fall down. After every earthquake you will read about building contractors being arrested for not putting up their buildings properly. It is the same I think with genetically modified foods. We may get problems in the future, but I think we can expect most problems will occur rather faster with these agricultural products simply because the thing will be grown on such a large scale that it is likely to produce the products. So I think they are more on the sort of timescale that this document is talking about, seven years. Again, to come back, Lord Reay, to what is wrong with this document, a fixed seven year period, a fixed moratorium of seven years or fixed monitoring or anything fixed for seven years, does not strike me as sensible. There are cases and cases. In some cases you will say, "It is indefinite, so we are going to have to monitor until we are satisfied it is right." In other cases you say, "We do not expect anything, it is a fast reproducing plant, three years will be more than enough, possibly two might do." You have to examine your cases and have your reaction ready. Coming back to an earlier answer to Lord Willoughby de Broke, it was a question of companies taking out insurance for the future, if this comes from something they have produced. This is something like product liability of a sort. They need to be able to bring up enough financial resources to try and rectify it. Does that answer about regulating for disasters?

The moratorium: Lady Young's organisation has called for a moratorium. I had faxed to me on Friday

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[Continued]

[Lord Gisborough Contd]

their two-page paper calling for a moratorium, *Position Statement on Genetically Modified Organisms from English Nature*. They called for a moratorium on the grounds that certain sorts of research should be completed and analysed before we go forward. I also got on Friday from the Department of the Environment, Transport and the Regions, a list of current projects they are looking at, and these are all very useful projects and will help us improve our knowledge of risk assessment, but I do not think they are the sort of projects which would justify calling for a moratorium. People always say, "Let's have some more research". We know a lot more now than we did ten years ago, in another five years' time we will know more again. I think the answer is not a moratorium for that sort of problem but a limited licence and, as I suggested for the Novartis corn-borer, they should be given at most a limited licence until they can produce a better product. In general, we need moratoria on things where we see some problems or where consumer confidence is worried. There was a report in *Nature* where some food company suggested a moratorium might be a desirable thing to improve consumer confidence. I am quite sure that we do need some action at the moment to improve consumer confidence. He suggested a moratorium would do that, I think if we have a moratorium for three years all that will happen is that we will have the same lack of consumer confidence bobbling up in three years' time. I think it will only defer it. I think we do need to take other action to improve consumer confidence and I can suggest ways in which companies could do this. In the case of Novartis, they could say they will replace the corn with one which does not have this antibiotic resistance gene in it and that is a proposal and they would withdraw it from the market. In the case of Monsanto, my no doubt unwelcome advice is that they should stop spending £1 million on advertising and spend it instead on segregating modified soybean from unmodified soybean. It is not that I think myself there is any risk from modified soybean, but I do see that the European consumer is gravely affronted by not having any choice on the supermarket shelves. To improve consumer confidence in that field, you have to restore his choice and no amount of advertising is going to do that.

Chairman

535. Presumably, if there was to be a moratorium, there would be no opportunity to have those large scale commercial trials which you consider to be essential to gather the information one should have about the risks these crops may pose to the environment?

A. That is correct, Lord Reay. I see a moratorium as merely a way of deferring the problems we have at the moment and we would then have to face them again. I suppose, as we all have a limited lifespan, if we could defer everything for 50 years, it would be somebody else's problem, but I do not think that is the way we should go about public policy. I think if we have a problem we should tackle it rather than try to defer it. So I am sorry to disappoint Lady

Young, but I do not support the call for a moratorium. I do understand why it has been called for, and I do think that the public concern/consumer confidence issue is one that does have to be addressed, but I think it should be addressed in other ways.

536. Would you perhaps like to say a little more about that? It is only now in our discussion today that we have touched on the question of consumer confidence. I am sure you have given it some thought in view of your belief, as you have stated it to us, in the technology. It plainly must be a concern for you that there is such a lack of consumer confidence in and support for the technology. What measures would you recommend for improving public confidence?

A. Again, if I can put in evidence a paper by Burke, who was chairman of the Advisory Committee on Novel Foods and Processes until a few years ago. He wrote a short article in the *British Medical Journal*, two sides. I do think we want to look carefully at the regulatory system, we want to make it transparent, which I think is the jargon, to make it publicly accessible. We do also want to make sure that the regulators ask appropriate and sensible questions, that the answers to the questions are out there, that if they have set up a system and some section is not happy with the answer then there should be some sort of appeal procedure where you can go back and have a look at it again. There are all these sorts of issues. It is not my field, my Lord Chairman, but I do think people who are experts in public policy do know how these sort of things should be done. If I am allowed to introduce this from my wife's field, which is consumer confidence in medicine, (she is a patient representative at various of the Royal Colleges), and there there is a question of how you inform the patient of what the risks are of what might be offered to them so they can take a rational judgment. This comes back to the soybean. People are not at all worried about genetically modified tomato paste because there it is on the supermarket shelf and it says, in rather large letters actually, "This is genetically modified paste", and if you say to yourself, "I am not happy with that technology, I do not really trust the scientists, I do not want to buy it", you can buy the tin next door. So for the time being we must ensure there is consumer choice available so that for most consumers who are going to be satisfied that the technology is safe and the regulators have done the right thing, they can go ahead and buy genetically modified food, but they need to know they are buying genetically modified food. For those who, for all sorts of reasons, still have worries, then you are going to have an alternative food. There are problems coming up here. There is the fish gene for cold hardiness which may find itself in crops and I am sure there are going to be people who do not wish to have anything of any animal origin, who are going to object, and they are going to want to have a choice of buying products which have that particular fish gene in. I would say at a

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[Chairman Contd]

straightforward biochemical level that they are misguided, but I can see on an emotional and human level it is their choice and they are perfectly entitled to that view.

Lord Jopling

537. I wonder if you could tell us whether you have any misgivings at the news this week that Monsanto has acquired Plant Breeds International, which is formerly, you recall, the old Plant Breeding Institute and the National Seed Development Organisation at Cambridge? Does that worry you in any way?

A. Yes, I would say that the activities of Monsanto are worrying quite a lot of people but I do not know that that is a matter for me as a person or for this Committee. People do see a danger in monopolistic activities, I think that is a general worry they have. I think you can say in another field, in computers, there are a lot of people who are very unhappy at Microsoft's behaviour in directing its monopoly, but that does not mean they are not going to go and buy Microsoft goods because they, after all, do the work and there may not be alternatives. I think there is always concern where there is the appearance that a company is going to be putting itself in effectively a monopolistic position. I

think there are concerns about that here, voiced by my colleagues in informal discussions about Monsanto, that they do see it driving the field by acquiring a large number of companies. They are also concerned about some developments and the effect on developing countries, they are concerned about developing countries being beholden to companies in developed countries, to multinational companies. These are general concerns, they are not really anything to do with the ecological risks of genetic modification.

Chairman

538. Professor, I think that brings us to the end of the questions we wanted to put to you. May I, on behalf of the Committee, thank you very much indeed for having taken so much trouble with your evidence and giving us an exceptionally interesting hour and a half. You have given us any amount of interesting information and argument, you have carried us down fascinating byways with plenty of lateral thinking, and with many interesting and amusing analogies. We really could not be more grateful, thank you very much indeed.

A. Thank you very much for inviting me, Lord Reay.

WEDNESDAY 14 OCTOBER 1998

Present:

Gallacher, L.
Grantchester, L.
Jopling, L.
Moran, L.

Rathcavan, L.
Reay, L. (Chairman)
Wade of Chorlton, L.
Willoughby de Broke, L.

(The Food and Drink Federation's written evidence is printed on pp. 331-334)

Examination of witnesses

MR IAIN FERGUSON, Chairman, Food Policy and Resources Committee, MR NEVILLE CRADDOCK, Chairman, Scientific and Regulatory Affairs Committee, and DR GERALDINE SCHOFIELD, Novel Foods and Biotechnology Sub-Committee (of the SRAC), the Food and Drink Federation, called in and examined.

Chairman

539. Good morning, welcome to our Committee. May I thank you very much indeed for having come to give evidence to this Committee in the enquiry it is conducting into genetic modification in agriculture. You have also very kindly sent us some interesting evidence. Perhaps I could start by asking you to say whom you represent within the food supply chain and perhaps at the same time you could state, for the interest of the Members of the Committee, to what companies you are linked as individuals, if indeed you are linked to companies.

(*Mr Ferguson*) Certainly, my Lord Chairman. If I could introduce myself. I am Iain Ferguson and I chair the Food Policy and Resources Committee of the FDF which is a committee that, as its name suggests, looks at the policies regulation as it affects our industry. It is a committee composed of 15 chief executives of the major food companies. I also represent Birds Eye Walls, I am the Chairman of Birds Eye Walls, which is a division of Unilever.

(*Dr Schofield*) Geraldine Schofield, I chair the Novel Foods and Biotechnology Sub-Committee of the Food and Drink Federation. I am actually a research scientist and by background a microbiologist. I am Head of Regulatory Affairs, Foods at Unilever Research, based in the United Kingdom.

(*Mr Craddock*) I am Neville Craddock, I chair the Food and Drink Federation's Scientific and Regulatory Affairs Committee which is the principal technical, scientific and regulatory committee and comprises the chairmen of the FDF's specialist sub-committees, of which Dr Schofield is one. My permanent employment is with Nestle UK where I am the Group Regulatory and Environmental Affairs Manager responsible for the legal compliance of Nestle's United Kingdom Business and external representation of the company in respect of environmental and regulatory developments.

Chairman: Thank you very much.

Lord Gallacher

540. Mr Ferguson, do the genetically modified products currently on the market benefit you as manufacturers? What modifications would be of most value to you? Are you indicating these ideas to your

suppliers? When do you expect such modifications to be on the market, either in the United States or the EC?

(*Mr Ferguson*) Thank you for the question. Just as I answer it, would it be helpful to describe who the FDF are or are you confident of your knowledge of the FDF?

541. I think it would be useful for Members of the Committee, Chairman, to hear who they are for those of us who are not familiar with them, of course.

(*Mr Ferguson*) If I can very briefly then just say that the FDF represents the United Kingdom food and drink manufacturing industry. It represents the companies of 45 different sectoral trade associations. It brings together those trade associations. We account in the United Kingdom food manufacturing industry for 22 per cent of the purchases made by United Kingdom consumers and we are responsible for using 70 per cent of the output of United Kingdom agriculture. We employ in our businesses directly around 500,000 people and the gross annual output of the industry is about £50 billion, so it is a substantial business. We do represent the food chain through from suppliers of ingredients, and they can be very small companies, to the big manufacturing companies, so we cover the whole chain. In terms of your direct questions, the products of genetic modification which are on the market today are essentially those where the benefits are derived by those earlier in the supply chain, by the growers and by the farmers principally. They are essentially modifications which help in the growing of the crops. As manufacturers there has only really been one product which is genetically modified rennet called Chymosin which is used in cheese manufacture which has had a direct influence on the way that we produce foods today. In fact, that genetically modified rennet is used in over 90 per cent of cheese production today in this country. Perhaps I could pass over to my colleagues to answer the other questions.

(*Dr Schofield*) My Lord Chairman, as Mr Ferguson said, most of the ones we are seeing have had agro-economic benefits. There have been some innovations in processing, mainly enzymic. What we are looking at in the food industry are particular areas of functionality, combining lots of the sciences, including nutritional science, as well as genetic

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MR IAIN FERGUSON, MR NEVILLE CRADDOCK
and DR GERALDINE SCHOFIELD

[Continued]

[Lord Gallacher *Contd*]

modification and other techniques: plant physiology and biochemistry. We are actually looking at things like modifications of oilseed rape by cutting out a processing step and other oils which have health benefits, particularly modifications of starches. There is quite a long list. For example, Isoflavonones in soya beans. Soya beans are an extremely good source of protein and although we know they are nutritionally beneficial there are some anti-nutritional compounds in there. If we could reduce those we could actually benefit from soya beans in a different way. We have to process at the moment in order to obtain some of those benefits. The food industry, particularly the manufacturing industry, is looking at products which are going to have considerable consumer benefits.

542. Any indications to manufacturers?

(*Mr Ferguson*) Perhaps I could comment on that. One of the things which needs to be understood is that we are dealing with a global supply chain. The production of the majority of the crops that we are talking about at the moment in genetic modification, things like soya and maize, are international crops which are grown on many different continents and they are internationally traded as commodities. As United Kingdom manufacturers we are sourcing raw materials from a very wide range of sources, therefore the number of companies which are involved in the supply chain is large. In terms of indications of the general types of improvements which would be ultimately of consumer benefit, those are clearly fed back through suppliers and, of course, the main suppliers, the main biotechnology companies too, employ people who have a knowledge of the food industry and of nutrition, so there is an interchange of information. We have compiled a small *aide memoir* of facts and figures on transgenic crops as they are today to underline the fact that this is an international sourcing issue, the crops are grown internationally in many different countries now. We have also laid out some of the expectations about what the next crops are likely to be as they come forward into production which we hope might be of some help to you.

Chairman: Thank you. We will study those, that is very helpful.

Lord Rathcavan

543. Can I ask you about food safety? Do you have any concerns at the moment about the safety of GM foods? Do you think allergenicity is a potential problem? Do you think that the safety of GM foods is better or worse regulated than other foods?

(*Mr Ferguson*) I would like to ask Mr Craddock to answer that question.

(*Mr Craddock*) I think we would start from the premise that for the food industry safety is effectively non-negotiable; it is a given, not only in our own operation in providing products for the consumers who are clearly fully entitled to expect such, but we also as producers, processors, expect the same with our raw materials. We base this as part of our fundamental credo with a twin pillar of full, meaningful and relevant information. Through that, we then allow the

consumers to make a full and informed choice as to the products they are purchasing. In terms of the specific question, I am not aware of any reason why we should consider the ingredients and the derivatives from the GM foods themselves to be inherently any less safe than any of the other developments which we have seen over many, many years. We clearly have to rely, and indeed we do rely, on the scientific rigour of the various approval processes around the world. My colleague mentioned the international trading nature of our business. GM—genetic modification—is global and so indeed is the assessment of these products. We are confident that the mechanisms are in place to pick up any suggested reasons for lack of safety or any lesser degree of safety being mooted but I think, to date, certainly these have been picked up by the scientists and the peer review of the work that is in hand.

Chairman

544. So from your point of view you are satisfied with the working of the existing regulatory system in the United Kingdom?

(*Mr Craddock*) I would hedge my answer a little, my Lord, and say as it is operating at the present it appears satisfactory, but that is not to say there might not be improvements. I think one of the areas that we would very much like to see improved is in terms of bringing together the regulatory process and indeed the regulations themselves into a seamless whole. I know the suggestion has been made in other places for an overarching regulatory body, an overseeing body, which would pull together the various advisory committee structures, and I believe that is a suggestion that is worthy of some further consideration. We are not talking only of the safety of genetic modification; there are the ethical and the environmental aspects, and I believe we should be looking in totality rather than just in isolation.

(*Mr Ferguson*) I think perhaps we should make the point too that it is important that that is looked on at least in a European context. This is an international business, the sourcing is international, and it is impossible to compartmentalise this into a country by country approach. It has to be looked at over a broad spectrum. Then, of course, there has to be a mechanism for national interests, such as our own, to be fed into the European debate and then ultimately into a wider debate. Is your Committee aware of the Royal Society's Report on genetically modified plants? There is some very good argument in there which we in the food industry have contributed to and, in fact, Mr Craddock sat on that committee.

Chairman: Yes, the Royal Society's statement has been made available to us and has been circulated.

Lord Jopling

545. I am glad that you have referred to the Royal Society's statement, which we have. Could you comment on what you think is the adequacy of the regulatory system in the United States which is where most of the soya comes from? Do you think that it

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needs to be tightened up very much? Do you believe, as the Royal Society does, that there is need for a tightening up in the United Kingdom? Would you comment on the system as you see it in the United States?

(*Dr Schofield*) Obviously it is difficult to go into too much detail about the United States' system. If you look at the two systems—UK/European versus the United States—there are certain advantages in terms of the United Kingdom system in that you actually get specific approvals and specific approvals on field trials. At the moment in the United States there are a lot of field trials which are just going on by notification, without prior approval. From a regulatory and from a risk assessment point of view we are having those field trials pre-approved by an advisory committee. All they have to do in the United States is a thirty day notification. In terms of actual commercialisation, all of the data is actually published and open in the FDA registers and people can comment. Maybe one of the successes in consumer acceptance and perception in the United States has been the openness of the approvals that were given to some of these field trials which were actually openly published and the debate could be seen in the public arena. I think it is probably not for me to judge the Food and Drug Administration in the States as to whether their safety is there. I am sure that they would not release anything on which there is a safety question. It (soya) has been in the market now for two to three years and, as far as we know, nobody has recorded any health effects. In terms of the physical environment, it is so much different in the United States in agriculture and in Europe that I think it would be going a little too far to try and compare any environmental risks and benefits of those two systems.

Chairman

546. What is your view of the call which some are issuing for a moratorium on the commercial release of genetically modified crops?

(*Mr Ferguson*) I am very happy to comment on that. We believe that a moratorium would be unworkable. As we have already discussed we are dealing with an international sourcing base here and a moratorium on the cultivation of genetically modified crops in the United Kingdom would have little effect on genetically modified ingredients becoming part of food production in the United Kingdom. We can see a number of very negative aspects to a moratorium. It would make it very difficult to undertake field trials. If there is no research it is very difficult to build up bodies of evidence, which seems fairly self-evident. I think it could give us trading difficulties. We would potentially have some difficulties under the WTO arrangements. It would also inevitably drive up the costs of raw materials in the United Kingdom if we were doing something which was very different from the rest of the world commodity system. We are unclear too as to quite how it would apply, for instance, to imported finished food products and imported raw materials. It is very unclear to us just

exactly what could be achieved by a moratorium so we would certainly not support it.

Lord Wade of Chorlton

547. What do you believe can be done to improve the whole question of public acceptance of this technology? What is the FDF doing in order to assist in this? Would you agree, in fact, that your Foodfuture programme has possibly not gained the public awareness that you had hoped?

(*Mr Ferguson*) We welcome the opportunity to comment on this. First of all, we believe that this is a long-term issue. We are talking about a long-term need to make information unbiased, transparent information available to people. We do not believe that this is a quick fix campaign. The Foodfuture initiative is very much based on a long-term process of making available a series of publications, making available a website on the Internet which, interestingly, since it was launched about a year ago has had over a million visits. There is activity there. It is also about making available material for journalists to incorporate in their articles giving an unbiased source of information and running a whole series of exhibitions and roadshows. We have tabled a summary of the activities of the Foodfuture activities for your Lordships to look at afterwards. The feedback of the evaluation from people who have attended the Foodfuture various activities has been that two-thirds of those who have been there have responded to the questionnaires very positively saying that this is the sort of information they want and being able to discuss these issues with people who are knowledgeable in a way where unbiased and informed debate can take place is very helpful and very useful. We clearly believe that more of this has to happen. One of our worries is that there is a lot of material in the public domain now which goes back two or three years and this is a very rapidly evolving area of science, it is a very rapidly evolving area of business, and the saliency and relevance of some of the material which is in the public domain comes into question now two or three years after it was published. We continuously pick up issues where people are getting hold of information which was published two or three years, not realising that arguments have evolved and new evidence is available. One of the essential issues is to keep the debate moving forward. We see the Foodfuture campaign as being something that tries to be part of helping to do that. The IGD, which is the Institute of Grocery Distribution, which in a sense is the overarching body for our industry which brings together the retail sector and the manufacturing sector, has also been active in this area with publications and making available leaflets and booklets through the retail stores.

Lord Grantchester

548. Following that point up, are you content that the amount of provision of information to the public is adequate at present? Are you content that the debate is being conducted in a constructive manner? Might the provision of a unified information source be an

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improvement? Perhaps you might expand a bit more on how you see your role in this debate.

(*Mr Ferguson*) Yes, I will comment and then I am sure my colleagues would also like to comment. We fundamentally believe in making available information to help consumers make up their own minds, to make a choice. That requires a number of things. It requires clear, unbiased information and it also requires clear, unbiased labelling of products which has to take place in the context of clear, concise and universally applied legislation. All three things have to be in place before consumers can make an educated choice. We are very much involved in all three of those areas in the food industry.

(*Mr Craddock*) We have probably moved forward on to the issue of labelling and I would like to reiterate the point that labelling is not necessarily the only way of conveying the information relating to the use of this new technology and derivatives from it in food. Sometimes I think the debate does get a little bit channelled down the middle, that it is labelling, labelling, labelling. There are many, many other ways today, and increasingly there will be more with modern technology coming on line in stores, etc., to convey the relevant information about a particular product other than just in hard print on the individual packaging. That is an area to be considered for the future.

(*Dr Schofield*) The industry has also supported academic initiatives, such as the National Centre for Biotechnology based at Reading who do an excellent job of travelling around schools and providing information packs and so on. They were originally set up by the Department of Trade and Industry. There are lots of other people who help to support their work which is independent and I think they do an extremely good job in the education field. Probably more of that type of information would be very useful.

Chairman

549. Is there anything to be said for a single information source, a sort of national GMO helpline, which people could use to get information on the subject? Is that of interest or not?

(*Mr Ferguson*) Clearly there is an interest in the public receiving unbiased information. You can see that by the number of visits to the website of the FDF. The British Nutrition Foundation, which is a charitable organisation supported by industry and by the academic world, also runs a website which has had a similar number of visits. It deals with nutritional issues but it also deals there with issues of genetic modification. There is a large demand for this type of information. Some of the earlier Government publications, particularly the so-called MAFF Foodsense booklet entitled "Genetic Modification and Food", for instance, are now in a sense four or five years old which are guilty of being out of date and dealing with the debate as it was four or five years ago, talking about the forthcoming introduction of this technology rather than talking about the technology as it is in the marketplace. Any source of information of this type

has to be kept up to date. I think on balance if it were available, if there were a central point of information, it could only be a positive attribute at the moment.

Lord Jopling

550. There has been a good deal of publicity following the action of Iceberg in saying they would not use genetically modified crops in their own-brand products. Do you think that there is a future for segregating genetically modified foods or do you think that the whole thing should be market driven, as it clearly is in the case of Iceberg.

(*Mr Ferguson*) Thank you for your question, Lord Jopling. I think it is Iceland.

551. Iceland.

(*Mr Ferguson*) I think Iceberg is the thing that sank the Titanic.

(*Mr Craddock*) Or a type of lettuce.

552. I do not go shopping very often.

(*Mr Ferguson*) At least not in Iceland by the sound of it. The issue is quite complex. I would agree with you totally that segregation ultimately can only happen for two reasons. It can either be a requirement of law or it can be market driven; there are no other mechanisms which can achieve segregation. There are a number of very practical issues here and I would ask Neville Craddock, who is an expert in this area, to comment.

(*Mr Craddock*) I am not sure about the "expert" but I will certainly comment on that. I think you have given part of your own answer, my Lord. Yes, it would have to be market driven. The only way you would get statutory, mandatory segregation would be if there were perceived to be some degree of safety concern and then you go round in full circle: if there is a safety concern then the crop ultimately will not be released. Commercially, at the moment the principal driving force is the United States. They have made it abundantly clear up to Government level that they do not see segregation as a legal issue. We, therefore, are looking to ask whether we are talking of segregation of the GM crop or segregation of conventional, traditional strains and we are coming back now to looking at the latter. To be effective, whichever route you follow, the segregation has to be right through the food manufacturing chain, right through the supply chain. It is of little purpose to segregate just the crops and bring them in for further processing, you need to segregate totally the derivatives of these crops. Soya is processed into countless numbers of derivatives, as indeed is maize. These derivatives are our own ingredients and we have to attempt to keep those completely segregated throughout our manufacturing and trading chains. Some of these derivatives themselves are traded as commodities and traded internationally. I think you are beginning to see the very wide network of chains that would all have to be kept separate and ultimately one could envisage that, if segregation were to become the norm, you are talking of parallel processing streams

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right the way through from crop to finished product on the retail shelf; i.e., there would be two systems for producing Kitkats, or whatever products you would care to think of. Again, we have mentioned the complexity of the international level. It is one thing to think of doing it as a national thing, even worse if you go on to the international trading and manufacturing and import/export of finished goods. I think also one point which would focus very much back into the United Kingdom, in terms of segregation, is the commercial reality of today. We, as a company, and I know other colleagues in this room, manufacture in the United Kingdom for supply to what we might call third countries, and I do not mean developing countries. We are in competition for that business here, to get the business in the United Kingdom, against our own and competitors' factories elsewhere in the world; segregation will undoubtedly add cost. If we are producing goods in the United Kingdom for a market in which the GM debate is of no real concern, any additional cost which we put on to our manufacturing base in the United Kingdom will be reflected in the export prices, and quite honestly at the present time, with the high pound and other debates, with which I am sure you are extremely familiar, we cannot take that cost on to export goods. At the end of the day if we impose unilaterally within the United Kingdom an additional cost, it will certainly cost jobs because we will lose business on our export lines.

Lord Moran

553. Could I go back for a moment to what you were saying about the moratorium? You made your view very clear about a possible moratorium in this country. Does what you say apply equally to the possibility of a moratorium throughout the European Union?

(*Mr Ferguson*) Substantially, yes. A moratorium in one part of the supply chain only will not do anything other than potentially reduce the supply of genetically modified material; it will not remove it or eliminate it. One has to question what are the practical benefits of such a moratorium. From the food industry perspective we see no validity to this, we see no real benefits. If one then talks about public confidence, I think putting in place something which would be unlikely to be workable, and the fact that genetically modified crops—the majority of soya is grown in North America for the market here—still having soya coming into the European Community, into the United Kingdom from the United States, whilst there was a moratorium on growing it in the United Kingdom or Europe seems nonsensical.

554. Thank you very much. Now about traceability. Mr Craddock, I think, has already covered a good deal of this in his previous answer but I wonder whether you would be in favour of traceability for genetically modified crops and, if so, what this might cost and what the benefit would be? Can you tell us whether any other products are

traceable all the way from the farm to the retail shelf?

(*Mr Craddock*) I would like, if I may, just to add a comment in relation to segregation because I think in reality the segregation and traceability¹ debates are very, very closely linked. Whatever is done to segregate the crops at the present time is not going to be 100 per cent segregation. I think, Lord Jopling, you mentioned a particular retailer saying that they are using no GM ingredients. When you look into the issue of segregated crops it is physically, and indeed commercially, impossible to obtain 100.0 per cent separation, there will always be the adventitious presence of non-target crops in the streams. Segregation will not be the total answer, it cannot be. What we do need is absolute clarity in the current regulatory framework as to what is meant by a product which is below a threshold as far as the legal considerations are concerned in respect of labelling. As far as traceability is concerned, if I can move on to that, certainly there are schemes in place to enable traceable supplies but, as I have indicated, these are not pure non-GM material, they do cost and they are complex; there is a lot of bureaucracy related to them. I think that as far as the United Kingdom schemes are concerned, one with which we are familiar involves soya derivatives for the baking industry and maybe the next evidence this morning will build on this. The current US crop of soya is many tens of millions of tonnes. The United Kingdom requirement out of that is possibly at most seven million tonnes; I will be corrected if I am wrong. The segregated stream is measured in tens of thousands of tonnes. It is very small—if you will pardon the pun—the tip of the iceberg. It can be done but at a price and where there is a demand.

(*Mr Ferguson*) There is an example, I think, that it is useful to quote from seed production. In commercial seed production today the highest standards of purity are required in basic seed. That is where the generation of farmed C1, C2 seed starts. The cost of producing basic seed is roughly four times the cost of producing a commercial crop. That gives an indication of the cost of pure traceability and trying to guarantee a very high standard of agricultural practice so that co-mingling and any cross-contamination is kept to a minimum. It is a very, very expensive process.

Lord Jopling

555. I am sorry, I do not think, with respect, that answers the question that Lord Moran put to you because I think controls on breeding seed stock raise separate issues. Could you hazard a guess as to what the extra cost of soya would be if it could be traced as to whether it was non-genetically modified, bearing in mind that there will always be a bottom limit of tolerance of contamination, to use that word, with genetically modified product? Would you

¹ The FDF have understood traceability to mean the identity preservation system described to the Committee by Iceland and United Biscuits, as opposed to mandatory traceability for monitoring purposes.

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hazard a guess for us because I think it is very important in our enquiry as to just how much extra per tonne it would cost to have traceability?

(*Mr Craddock*) I do not think it is possible to put an absolute figure on this, my Lord, because at the moment the figures that are being quoted for adventitious presence, adventitious residues of a genetically modified crop, range from between two, three, four, even I have heard as high as five per cent mentioned. Clearly if the limit is at two per cent then it is possible to work through and say what is required in the way of dedicated transport, dedicated systems, dedicated mills, silos, etc. An exercise was done about two years ago which suggested that possibly a premium of 40 per cent would be required. Without knowing what the acceptable level of adventitious presence is, it is a little like saying how long is a piece of string? We are talking here a little about a dilemma; the existing figures are based on quality criteria relating to yellow maize in white maize, etc., but with the GM debate, we are talking of rather more ethical concerns; we are talking of something other than just pure quality of the product. Clearly if the segregation level were 0.2 per cent, even half a per cent, this would magnify quite dramatically the cost of achieving that level of segregation.

(*Dr Schofield*) The other question is that at each stage from farm through to processing you may have an added percentage each time. If you are talking about segregating the crop in the States and containerising it rather than shipping it you will have an on-cost there. If you are using that raw material for animal feed then that end cost remains there. If you are then taking a by-product of maize, for example, which at a much smaller level is producing added value ingredients then at each stage in that production where you have to keep segregation, you have to keep the process plant clean, you will add a cost at each of those stages. If you are looking at particularly value added maize products, starch products, the on-cost will be so much more than if you are just looking at the raw kernels themselves because at each stage you will have a cost.

Chairman

556. Could we move on to labelling. Could you say what your views on labelling are and what you recommend to your manufacturers? As I understand it from reading your paper you only consider labelling should be required if there is a practical difference in the end product. Could you confirm whether that is the case or not and explain what the implications of that would be in the present circumstances?

(*Mr Ferguson*) Yes, my Lord Chairman. Clearly at the moment labelling is an issue particularly made more difficult because there are not clear regulations and legislation in place. At the moment, as from 1 September, effectively our view is if there is soya in the product it should be labelled because there is no threshold provision. Therefore, if a product contains soya it may well contain genetically

modified soya for all the reasons that we have gone through earlier. Our advice and the advice of the FDF and its membership is if in doubt, label. That has been our advice consistently now for the last five or six months. We do desperately need a threshold level to be agreed because the threshold level, of course, is what will drive the labelling decision and it is also what will allow consumer choice to take place. If there is no threshold everything eventually ought to be labelled and that gives no consumer choice. If a threshold level is set at a sensible level, and people have talked about percentages, 0.2 per cent, 0.5 per cent, two per cent—I think there is a debate to be had about what the right percentage is—once it is set of course it then allows a clear labelling decision to be made and then gives the consumer a clear choice. In labelling we see the need to be very clear. There are three different things in a sense that can be labelled. A label can apply if there is genetic material there above a certain threshold. No label would appear if there was genetic material below the threshold. Certain people, and the retailer that Lord Jopling mentioned, wish to claim GM free. In our view that should be 100 per cent GM free and must be capable of being audited to be 100 per cent GM free. It is only by being absolutely clear about this that we can hope to build consumer confidence, which returns to a point we talked about earlier.

(*Mr Craddock*) May I just add something further. The debate is very much on labelling but, of course, increasingly we are seeing foods consumed ever more out of home; there is also a perception, I will put it no stronger than that, of superiority of the many products which are purchased over delicatessen counters, etc., so-called loose sales, and which are currently exempt from the vast majority of statutory labelling requirements. Clearly if we are majoring on labelling here for the ethical and emotive issue of genetic modification then labelling means something wider than just the food label on a pre-packed product. We have to find a means of addressing this and Her Majesty's Government is currently doing this in a round of consultation. We have to find a way for catering and loose sales being brought into the same framework.

Chairman

557. Do you see the labelling situation changing radically in the future? If the move is, as Dr Schofield was explaining earlier, towards products which are going to be modified in ways which are attractive to the consumer, it will be necessary to point out the purpose for which they have been modified and labelling will have a different information aspect to it. The choice that you are describing, Mr Craddock, is simply for the consumer as between whether they consume a food that is genetically modified or one that is not, irrespective of the purpose of genetic modification. Is that correct?

(*Mr Ferguson*) Yes, that is correct, but clearly we have already seen in the marketplace genetically

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modified tomato paste, for instance, a single ingredient and, therefore, in a sense, quite an easy example to label with claim of benefits for the consumer, and clearly as we go forward there may be other products of that type. Of course, most food products and most prepared food products contain quite a wide range of raw materials. As time goes on, a number of those will inevitably be genetically modified, for different reasons. Some will be like soya and maize, genetically modified because they confer an advantage on the growing and perhaps the processing part of the chain. Others may offer particular benefits to consumers which Dr Schofield laid out earlier. So there will inevitably be, as there is today, a whole series of different reasons why different raw materials are in a finished product.

(*Dr Schofield*) But, my Lord Chairman, those products which do have substantial changes would have to go through the Novel Foods Regulation, which makes the labelling provisions. So in the same way as with soya and maize now, they would have to be labelled. Obviously then the question would come of the marketing planning but they would have to be labelled legally in the same way as herbicide tolerant soya or maize would be, actually on the fact that it was genetically modified.

Lord Wade of Chorlton

558. The difficulties on labelling bring us rather neatly to my question on testing. Is the absence of a GM testing policy confusing? You mentioned thresholds, Mr Ferguson. What sort of thresholds would you like to see?

(*Mr Ferguson*) I think it is not so much the testing policy that we require, it is a validated method of analysis, and we are in an area here which is quite rapidly evolving. Tests are being developed today which allow for the testing of individual raw materials much more rapidly than the testing of a finished product, and I think in anything that we talk about we have to take account of the fact that testing methods will become more sensitive. It will also take a considerable amount of time to build up a body of statistical evidence, as we do with safety and as we do with a number of other areas in the food industry. We tend to work on a thing called HACCP (hazard analysis and critical control points). We manage quality through the process. We do not just test the finished products, we test as we go through the production process and over time one can build up a statistical picture of the performance of a manufacturing unit at each of its critical points. That takes a considerable amount of time. That will ultimately be the approach that will be used in this area, too. At the moment clearly many companies are having tests done. They are quite expensive—around £100 per sample—and there are relatively limited lab resources who can handle this, so it is quite an interesting time. You might want to add something to that.

(*Mr Craddock*) Not really, just on the question of the numbers, and the methodology and sensitivity your question posed, what sort of threshold. At the

moment I think the most adept laboratories would claim that they can detect to a limit of about 0.2 per cent. Below that it becomes a bit of, "It looks as if it is there but we cannot be sure," and if we are looking at quantification then I believe the current figure is somewhere around 1 per cent. In other words, if it is less than that you just have an open argument as to how much is there. So it is not quite the same as using the most sophisticated testing that exists for pesticide residues or heavy metals. We are not talking about being able to go down to parts per million or parts per billion at this stage. It is a sophisticated method but the results are still relatively crude, if you understand the apparent contradiction.

(*Dr Schofield*) Could I add, I think the other thing we have to remember is that testing is not an end in itself, it is a means. We should not look at testing as actually the end point. If, in terms of policy, we actually had the policies in terms of the segregation and the labelling and the whole of those things sorted, then we are using testing in a totally different way, as an audit trail and not as an end in itself. In this particular instance, because the levels of detection, as we know, are getting now, in raw materials, to 1 in 10,000, to 1 in 100,000 and it could even go beyond that, what we should be looking at is going back up this traceability/audit trail/HACCP-type route, and using testing as we do now, to verify those audit trails, is not an end in itself.

Lord Gallacher

559. Have your members come under any pressure from wholesalers, supermarkets or others for or against genetically modified foodstuffs?

(*Mr Ferguson*) This is different from the normal commercial pressure, is it? Clearly the whole food chain exists to satisfy consumer needs. If there is a perceived consumer need for a product which does not contain genetically modified material, people will seek to fulfil that need, and there are companies who have been making products which have been reformulated to take, for instance, soya out at the moment so that they can claim that they do not contain genetically modified material, but it is part of a normal commercial relationship.

Lord Wade of Chorlton

560. Are you happy—and I am talking now about the food industry—with the role of the bioscience companies in the production of GM foods, and what relationship does the food industry have with them, because their direct customer is generally the producer?

(*Dr Schofield*) Yes, we do have obviously through the scientific community, as well as through a business community, dealings with the people who supply us in terms of what research they are doing and what they are going to have to offer. I think there was a slight problem, particularly with the introduction of the products we have been talking

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about, with agronomic benefits, that there was a lack of understanding of how to market these initially, because a lot of these companies are not used to dealing directly with consumers and so on; they are used to dealing into commodities and they did not quite understand or fully appreciate or go through the whole of the food chain, as Mr Ferguson said earlier, in terms of understanding what the consumer wants, what the consumer needs and what the informations are. I think that was part of the problem with the marketing strategy. It obviously is changing and it is a different relationship with people who are looking at consumer benefits in the bioscience companies.

561. Does that suggest that perhaps the bioscience companies have not really appreciated the response of certain consumer groups to these genetically modified foods?

(Mr Ferguson) It is a fact to say that the American bioscience companies were surprised by the reaction in Europe. They were surprised because they did not have the same reaction in North America, where they had successfully introduced these products, and they believed that a similar strategy, which was essentially to build on the benefits to the growers and therefore create a stream of material, would also work in Europe. Clearly they have learned from that mistake and, indeed, are now quite active in a number of initiatives, some joint initiatives with the food industry, some initiatives within their own trade associations, in helping to make available information and contribute information to things such as the FDF Foodfuture campaign. Again it is an example of the fact, of course, that the majority of these companies are not United Kingdom companies; they are not even European companies, they are essentially global companies, often using the North American market, because, of course, it is the biggest agricultural market in the world, as their point of introduction.

(Dr Schofield) We have been working with them through the European industry associations of which both ourselves and the bioscience companies are a part. It is a positive step.

Lord Willoughby de Broke

562. What work are you involved in in creating a code of practice, is the EC or the United Kingdom Government involved, and why did the Institute of Grocery Distribution produce their code?

(Mr Ferguson) We are working as an industry. As I mentioned earlier, I believe, the IGD is the overarching body which brings together the retailers and the food manufacturers, and their particular work, which Dr Schofield is very much involved with, in putting together labelling guidelines, was really there to try and fill a vacuum. As we have already talked about, we needed desperately the legislation and the regulation to be in place. In the absence of that, in order to build consumer confidence we wanted to make sure that, as far as possible, everyone in industry was using the same

basic guidelines, so that we could build on that as part of our communication.

(Dr Schofield) We realised, both retailers and manufacturers, about four years ago that these genetically modified commodity crops would be coming on to the market and research was done about how to provide information and labelling. There was a hope that we would have had the Novel Foods Regulation several years ago but in the absence of that it was decided to have a voluntary code, and we did some consumer research with some focus groups to decide what the consumer wanted. At that point there was quite an upswell that they wanted any novel protein labelled and that is why the Institute of Grocery Distribution came up with their code of practice. Part of it was a realisation of commodities and part of it was the Novel Foods Regulation.

(Mr Craddock) May I add, my Lord Chairman, we do, of course, work with our own government, as do other interested bodies, and they are looking at the moment to formulate guidelines which will hopefully clarify some of the uncertainties of the new regulatory framework.

Lord Rathcavan

563. Could I ask you about the lack of an international agreement and particularly the lack of agreement within the European Union on the handling of GM crops and the use of GM crops. Is this causing your members problems?

(Mr Ferguson) Yes. If we go back to the beginning almost, it is an internationally sourced industry. It would be very advantageous to have one unified set of rules, one unified set of regulations, which were applied universally, fairly and consistently. That would make our jobs very much easier.

Chairman

564. Are you concerned about the delays that are involved in the EC regulatory system?

(Mr Ferguson) Yes, we are, my Lord Chairman. In a sense it causes uncertainties. It allows the things that Lord Jopling was referring to to happen. It allows a particular element or part of a business or a particular business to try to make short-term commercial gain out of exploiting a lack of certainty and regulations, which can only be done at the expense of the rest of the industry which is trying to follow a uniform path. We very much want to see regulations in place and we want to see even-handed and consistent enforcement of those regulations. We see that as a fundamental part of helping to build consumer confidence.

565. Do you think the revised Directive, 90/220/EEC, will improve matters?

(Dr Schofield) 90/220/EEC, if it was applied across the board as it stands and we have seen it in the United Kingdom, is actually quite effective at regulating the field trials and commercialisation.

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Certainly, as my own experience, mainly in the United Kingdom, has shown and also from my sister company in the Netherlands, that it can actually be applied evenly and fairly. I think the problem comes with a lack of understanding and harmonisation of data requirements across the EC in terms of 90/220/EEC, which has caused a lot of problems. It is also rather unfortunate that we are in a revision of 90/220/EEC at this time because it is going to increase uncertainty at a time when we are looking for more certainty. So over the next two years we may be seeing a lot of debate about the scope,

liabilities, monitoring, seven-year authorisation schemes, which I think is actually going to be rather unhelpful at this moment, certainly to industry and I am sure to the public, whom we have been assuring we have a good regulatory regime and now it has been taken apart and rel looked at.

Chairman: That brings us to the end of our questions. May I thank you on behalf of the Committee very much indeed for having spared the time to come and give us some extremely helpful and interesting evidence. Thank you.

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[Continued]

(United Biscuits' written evidence is printed on pp 404–405)

Examination of witnesses

MR STEPHEN PARRY, Group Technical Director, MISS JOANNA SCOTT, Head of External Affairs, and MR CLIFF MORRISON, Technical Director, Frozen and Chilled Foods, United Biscuits (UK) Limited, called in and examined.

Chairman

566. Good morning, may I welcome you to the Committee and may I thank you on behalf of the Committee very much for coming to give us evidence on the subject of genetic modification in crops from the perspective of a manufacturing company. Could I perhaps ask you to introduce yourselves and your company and, in doing so, perhaps you could say how far up and down the food chain you extend? Do you do, for example, any farming yourself? If not, do you have links with farmers, or do you only purchase your raw materials? At the other end of the supply chain, do you have any direct outlets to consumers?

(Mr Parry) Thank you, my Lord Chairman. My name is Stephen Parry and I am the United Biscuits Group Technical Director.

(Mr Morrison) I am Cliff Morrison and I am the Technical Director of United Biscuits Frozen and Chilled Foods, which is a division of United Biscuits.

(Miss Scott) I am Joanna Scott and I am Head of External Relations at Group Headquarters.

(Mr Parry) To put in context your question about United Biscuits and its relationships, we actually do not own any farms but clearly we do, source ingredients and components from that particular supply base. Our company is an international food business operating in 21 countries. It has a total of 46 manufacturing sites worldwide and its products are available in more than 90 countries. We employ more than 20,000 people worldwide, of whom a significant proportion—16,000—are based in the United Kingdom. McVitie's Group is the third largest biscuit company in the world and, together with UK Foods, makes up the United Biscuit group of companies. As an individual company, we are a major member of FDF and have supported the Federation's position and I would certainly like to put forward our perspective on these issues this morning. I just wondered, my Lord Chairman, if I could make some introductory comments before the detailed questions in the opening minutes, which would provide a framework to our position as a business.

567. Yes, please do.

(Mr Parry) Thank you. The topic of genetic modification in agriculture is an important one for us. Managing the production of genetic modification of food is clearly a global issue and, like other manufacturers, we recognise that it can bring benefits to both society and to consumers. Product safety is, and always will be, however, our priority. We will, therefore, only use GM ingredients provided we are confident they are approved safe. We do have concerns, however, that the introduction of GM food in agriculture while it remains little understood may cause anxiety and confusion among our customers and

consumers, and while that happens, acceptance of foods containing GM ingredients may be poor. We recognise consumers' attitudes to GM in the United Kingdom and across many parts of Europe, as surveyed by Eurobarometer, indicate a low level of trust regarding scientific and government approval of this technology. We emphasise that scientifically based regulations alone will not guarantee consumer acceptance. That can only be, and must be, achieved through a broader policy of providing information and advice. As far as our own business is concerned, we continuously monitor consumer reactions on all issues by our Careline telephone services, and I thought it might be helpful to give one or two statistics in that context. Based on the volume of calls we have received, GM foods appear to be of less concern to most consumers than media coverage might sometimes suggest. In the nine months since the beginning of 1998 our various Carelines throughout the whole of the business have taken over 43,000 calls from consumers on a wide range of topics and issues of interest. Of those 43,000, a small number—1.4 per cent.—have related to GM. Whilst this is hardly a scientific sampling it does support our previous statement that media coverage can suggest a degree of consumer concern which is some way from reality. Nonetheless, United Biscuits recognises that some consumers are concerned about genetic modification and believes that consumers clearly have the right of choice. We enhance the right of choice through three elements: first, sourcing traditional crops with clear traceability; secondly, labelling those foods containing GM ingredients as required by law, and thirdly, supplementing label information through our Careline services. In making this short presentation, I wish to emphasise, however, that, first, even when we have sourced traceable, traditional crops, testing has shown that up to 1.5 per cent. GM material can still be present. Clearly isolation and/or separation are not totally succeeding, even when the supply chain goes to extraordinary lengths to secure these supplies. Secondly, the industry urgently needs clarity in the area of a *de minimis* level, which has already been referred to by our FDF colleagues, as well as agreement on a list of ingredients which do not require labelling. It is argued by some that we should label a product which contains an ingredient derived from a GM source irrespective of whether GM material, even only in trace amounts, is actually present in the product as consumed. Such a view, we believe, works strongly against consumer choice. If manufacturers are to make strenuous efforts and incur considerable expense to source these traditional crops and so provide consumers with choice, then only to find that there is trace presence of GM material, the dilemma is clearly whether or not to label. An approach could be that

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[Continued]

[Chairman Contd]

such foods would be labelled. However, this would result in blanket labelling and ultimately offer consumers no choice at all. Therefore, in conclusion, there would be no incentive for manufacturers to source traditional supplies if they found themselves being required to label the presence of GM ingredient, whether it can be detected or not. I should stress that none of our attempts to source traditional crops reflects any belief on our part that we do not think GM foods, where approved, are safe. They reflect our aim to provide consumer choice. We very much hope that the influence and reach of this Committee can help achieve more certainty and clarity than currently exists. Thank you once again for your invitation to present, my Lord Chairman, and we welcome the opportunity to answer your questions.

Chairman: Thank you. We would like to go through some of those issues one by one and we have some specific questions to ask you.

Lord Gallacher

568. Mr Parry, do the genetically modified products currently on the market benefit you as manufacturers? What modifications would be of most value to you? Are you indicating these ideas to your suppliers, and when do you expect such modifications to be on the market, either in the United States or in the European Community?

(Mr Parry) Thank you for your question. I think Mr Morrison should answer that particular question.

(Mr Morrison) My Lord, the answer here is yes and no. Currently there are four kinds of genetic materials approved here in the United Kingdom. We use one of these extensively and that is vegetarian cheese using genetically produced chymosin, which is the enzyme, and the benefit of this is that the cheese is available for vegetarians because the chymosin is a replacement for the calf rennet. We have been using this material for some time now and it has, over the last three or four years, gained in popularity to the extent that I believe that well over 90 per cent. of all cheeses now are produced by this method. It has benefits in terms of reproducibility, consistency and quality over the rennet-produced cheese, so there are clear consumer benefits with that particular product. The second GM product, of which you will no doubt be aware, is the tomato paste. Whilst that is only available via retail outlets at the moment we could see benefits in using that particular material in terms of consistency and quality and also potentially in price. So we do appreciate that the tomato paste has consumer benefits. As to the other two currently available, the maize and the soya, we do not see any benefits to ourselves or retailers or consumers at this time and the benefits, I think, definitely go back to those of yield for the farmers and of environmental benefits, although no doubt in due course we could well see the benefits of that coming through, but certainly not at this time. In fact, it is almost the opposite for us because we are very keen, as Mr Parry said, to source traditional crops and in doing this we have a significant on-cost at this time following through traceability, etc. So it is almost a negative

impact for us. Particularly, as Mr Parry outlined, there is this issue of a low level of contamination of GM material in the traditional crop and if we had to label at these low levels then, in fact, there is no benefit to us to go to this large and significant undertaking that we are currently doing to source them. Looking to the future, then yes, no doubt the second generation of GM crops are going to have a benefit and you have already heard about the potential nutritional values that could be modified into crops and particularly into oils in the future, and we also are aware that potatoes, wheat and sugar beet are coming along as well in this country. All those are going to have both environmental and nutritional benefits, we hope, in the future, but we are not directly influencing this at the moment.

Lord Rathcavan

569. Could I ask about safety? Do you share the public's concerns at the moment about the safety of GM foods, particularly in relation to allergenicity and antibiotic resistance?

(Mr Parry) We are convinced that GM foods, once approved, are safe. The approval process of governments, both here and in the EU, and their advisers certainly appears to us on the basis of following the debate and taking expert advice to have been scientifically rigorous and we are confident in the outcome, but perhaps Mr Morrison can expand further.

(Mr Morrison) Yes. Obviously consumer safety to our company is absolutely paramount and we do, as Mr Parry said, have confidence in the United Kingdom, particularly in the regulatory and scientific advisory committee processes. You referred to the antibiotics marker and I think that that has now been seen as being unnecessary. The antibiotics marker was there effectively to show that the GM has taken and there is no need for that and I am sure that future products will not have that marker in place. There are other alternative markers. So it is there at the moment but we will see that rapidly disappearing, and whilst we are not directly involved, we do take scientific advice in the area of safety in total. The Royal Society summary, which addresses this issue as well, has already been mentioned this morning and we are very supportive of that total document and its approach.

570. I think you are right. The Royal Society in its recommendations does indicate the undesirability of using antibiotic resistant marker genes. Would it not help consumer confidence in this whole subject if antibiotic resistant marker genes were banned?

(Mr Morrison) Speaking personally, yes, I believe that would be the right way to go. Yes, I would agree with that.

Lord Jopling

571. Are you not in some ways talking in opposite directions? Mr Parry tells us—and I did write it down, "We are convinced that GM foods, once approved, are safe." That is what you said on the one hand and yet the Royal Society says: "The Society has also some concerns about the regulatory processes governing the

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[Continued]

[Lord Jopling *Contd*]

development and use of GM crops." Surely you cannot have it both ways if you say you strongly approve of the Royal Society's suggestions and then you say that GM foods, when approved, are safe. Is that not a bit of a hostage to fortune?

(*Mr Parry*) I think we are referring to the mechanism.

(*Mr Morrison*) Yes. I think on the one hand the Royal Society paper covers the whole aspect of growing and environmental issues and the food as well. They are two separate issues and I think we are particularly applying ourselves to the food because we are not able to influence the growing aspects of the crops, which are different from the end food products.

Lord Wade of Chorlton

572. Could I ask what you believe could be done to improve the public acceptance of gene technology?

(*Miss Scott*) In our view, we believe it is always more difficult to win over public understanding and acceptance of a new technology if there has not been prior and adequate information and public debate. Whilst we acknowledge that there have been considerable efforts in recent years to promote public understanding of this very complex issue, sadly the reality is that there is a low level of awareness and understanding amongst both consumers and opinion-formers and, therefore, we feel that this new technology has suffered from inadequate information and public debate. In addition to that, the public's distrust of industry and government and now scientists as a result of BSE perhaps means that the task of winning over public acceptance is even more challenging. We also feel that the media have a very powerful and pivotal role in gaining public acceptance. They of course through their actions can promote public confidence but they can also hinder and damage public confidence and, therefore, acceptance. We therefore look to the media to be excellent communicators and ensure that their messages are always balanced, up-to-date and accurate, and therefore we feel that the media can help win over public confidence on this issue, but we also recognise that this is something we have to be patient about. We have to persist. It is not a "quick fix"; it is going to take a long time. Finally, on this question, again to pick up on Mr Parry's opening comments, based on our own consumer Careline monitoring we do not feel that consumer concern is as significant as some reports might suggest.

573. Could I follow up on that? You have identified a number of the problems. Do you as a company take any action to try and educate people more effectively? What action do you take to try and make sure that media reports are more accurate?

(*Miss Scott*) Obviously as a company we are very responsive to any questions and enquiries that we receive from consumers, public interest groups and the media. We will always ensure that we respond to any enquiries and provide whatever information is requested. We do that through our carelines but also in responding to media enquiries, in attending

conferences and public debates. That is what we do from our own company perspective. In addition, we actively support trade bodies and organisations which are helping inform the public. Specifically, we support the FDF's Foodfuture programme and we have also been a party to the IGD which was referred to earlier, in the development of their voluntary guidelines. So we are active in promoting public information and debating platforms through our trade bodies.

Lord Grantchester

574. This has largely covered the question I was going to ask. Perhaps I could ask for further clarification of your last statement, that you get actively involved through the FDF. Do you proactively go out yourself and provide extra information rather than only through your trade body? Do you consider the level of information to be adequate at the moment? Might it be improved by a more over-arching information source, perhaps a higher body again?

(*Miss Scott*) Lord Chairman, yes, indeed, and we always will provide consumers with information. We do as a company have a number of information materials and leaflets as well as relying on our trade bodies' materials. On your question about a single source of information or an overriding body, we believe that a single source of information could have some merits. For example, it would ensure, or help to ensure, that there was avoidance of duplication of effort and consistency of message. Also we have to remember that the resources, the financial resources and the people resources, in this major information role are significant. So a single source might be helpful. I think the reality is that it is probably not feasible and also we would question why we would do it on this particular issue when we do not do it on other issues. We would also point to the Food and Drink Federation's Food Future initiative as actually being very much an umbrella campaign or umbrella initiative. The campaign has in particular sought to work with partners such as the BBSRC, such as the Ministry of Agriculture, such as the Science Museum, and working with those sorts of partners has helped to provide a credible basis, an accurate basis, ensuring that the information is kept up-to-date and is obviously, therefore, perceived, or hopefully perceived, by the consumer as an authoritative source of information. But I guess the bottom line is that we could always do more and we need constantly to review actions and do as much as we can to help inform the public.

575. Do you think there has been any change in the public perception of genetic modification over recent time? Would you agree that it is very much the pressure bodies against the technology and the general public slightly ambivalent? Do you think there has been a change?

(*Miss Scott*) My Lord Chairman, again to go back to our consumer Careline monitoring, which we stress is not a scientific survey clearly, we have relatively speaking a low level of enquiry, which would indicate to us a low level of concern. It does appear to blip

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[Continued]

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marginally. We may be talking about receiving 50 or 60 calls the day after a *World in Action* programme or the day after a major announcement, but compared to the number of enquiries or calls that we would get on other issues, it is still a very small number of consumer enquiries to us. Whether that is, as I say, an accurate assessment is difficult to say.

(Mr Parry) Outside of those specific incidences, there seems to be an underlying level that is broadly consistent and constant.

Chairman

576. An underlying level of what—concern?

(Mr Parry) There is an underlying enquiry through our Careline services that seems to be at a fairly consistent level outside of the particular separate incidences to which Miss Scott referred.

Lord Rathcavan

577. May I ask a more general question following this question of public confidence and safety. Is not the problem that the only product which consumers can see as a real, genuine GM product is tomato paste, and also vegetarian cheese, but vegetarian cheese is less identified as being a GM product. The public concern is more with GM soya, which can find its way into pizzas and virtually anything else, and they feel they can go into a pizza shop or restaurant and find they are involuntarily eating GM soya? With this product there is no price benefit coming through yet to the consumer. Surely this is the key to consumer acceptance, as it has been in tomato paste, which I believe is 20 per cent. cheaper than traditional tomato paste? You have already said that the current benefits of GM technology in maize and soya are going to the farmers, although when we met the Soya Bean Association of America they had not seen much financial benefit yet: it seems to be going to the biotech companies at the moment. Do you hope to see the cost benefits coming through in due course and will that encourage more public acceptance?

(Mr Parry) Our personal view is that certainly there is no apparent price benefit as yet seen by the consumer, that certainly the benefit is so far at the supply chain and is all front-loaded. So our answer to your question is yes. As far as the perception of the consumer in the longer term is concerned, assuming it starts to come through in terms of the price benefit, then that could well have an influence. Certainly in the tomato paste context it is highly visible, that it is what it is. It is highly visible that there is a price advantage. Equally the consumers have the right of choice and make that choice accordingly and the statistics would suggest that where there is that visibility and clarity then there are a number of consumers who make the decision based on the price relationship. But I think that comes back to a consistent theme which is certainly true with the FDF submission as well. It is about this clarity and visibility.

(Miss Scott) Could I add one further comment on that. It is not just necessarily the price advantages but there need to be perceived advantages to consumers,

and with the tomato purée, although the price advantage is the key element perhaps, I think a lot of information has suggested that there is actually a quality and taste advantage as well and that sales of the GM tomato paste have actually outstripped the traditional tomato paste. So whilst price might be a benefit it is also a quality and other consumer benefit that we hope to see coming down the line.

Lord Jopling

578. Turning to segregation to which you referred in your helpful opening statement, but whilst you have been sitting at the witness table you have provided us with a document from Spillers Premier Products. It would seem from the evidence in this that there is a good deal of public demand for segregation. The document quotes *Nature* a year ago: "According to surveys, up to 85% of European consumers would shun genetically altered foods if given the choice." Spillers summarise their operation: "Spillers Premier Products is leading the field in the segregation of non-genetically modified soya beans. The Canadian operations are supervised by Manna International Inc., specialists in Identity Preservation for organic produce. Utilising a similar traceability system to that well established in the organic industry, Manna follows the soya beans from seed certification to the point of shipment. On arrival in the UK, Spillers Premier Products ensures that the audit trail is maintained from the port right through to the soya mills." That seems to suggest, on top of the Iceland experience, that segregation is possible and there is a public demand for it. And, if I may say so, with hard wheats or with malting barley there is a long tradition of segregation in international trade. Do you not think that, in view of the clear public concern about genetically modified foods, there is a case for encouraging segregation?

(Mr Morrison) Spillers are one of our sources for this traditional material. In addition to the flyer you have there, there is a very significant audit trail backing that whole product up from Canada. One of the advantages of Canada is that because the climate is cold there are no volunteers and the seeds are killed off over the winter, so that the product that you grow is actually—I would hesitate to say 100 per cent. but it is certainly a very pure material. But you will also notice in this document that Spillers will not guarantee that it is GM-free. You mentioned segregation of other crops and if you think about the ones that I am particularly aware of, durum wheat, the separation of hard and soft wheats, there is there a 2 per cent. tolerance, I believe. Other crops and other organisations can go up to 4 per cent. of contamination of the crop. In fact, in this whole area of segregation, as Mr Parry mentioned, we are trying to source traditional crops and whilst we have not had technologies followed through on the Spillers one (although since they have done such a good document I thought it was well worth putting forward) we have ourselves travelled extensively over this year to North and South America and to the Continent looking at traceability and we have gone to great lengths to try and establish traceability. If my Lord Chairman would

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[Continued]

[Lord Jopling *Contd*]

permit, I do have a couple of overheads I would like to put up. You already have hard copies of these.¹ I do not want to go through these in total detail but obviously we need to establish, to start with, that there is segregated seed. It is absolutely vital that we do that, and we then need to establish a paper trail, invoices, etc. all the way through to the grower to make sure those seeds are the only ones that are actually used. During the growing and the harvesting, and I am aware that some of your Lordships have an interest in farming—you will be aware these days that harvesting is by contract, so that a harvesting machine can be working on one farm one day and another the next and what we are going to have to do is to make sure that cleaning is 100 per cent. effective on that equipment in order that we are not going to get any contamination from a GM to a non-GM crop, and we effectively follow the integrity all the way through, right through to the port of shipping. This audit chart relates to soya, I might add. If you think about some of the issues on silos in the document that I have given you, you can see that some of those silos are 1,000 or 2,000 tonnes in size and they are all connected by elevators. What happens is that when the product is shipped to the United Kingdom, elevators will be used in sequence to fill the container ship. Some of these container ships can carry up to 50,000 tonnes of soya, so you have to make sure that you have a risk-based checking system, audit system, all the way through, that the correct elevators are used, the correct silos are used, the system is fully cleaned, etc. I believe that Spillers in fact only use small shipping containers of 12-18,000 tonnes and not 50,000 tonnes, and that, of course, is going to put an on-cost on. If you are getting a segregated crop and then using a 50,000-tonne shipping container, obviously some of that material in the ship will be non-GM and some will be GM and we need traceability all the way through. What you also need, in addition to the paper trail and the cleaning criteria, etc., is to carry out testing. What they tend to do in the States is to test by germination systems, so they take clean seed and they treat it with whatever material the herbicide is, because we are talking here about the soya herbicide. They treat the seed with that and then germinate it and obviously if there is no germination then there is non-GM seed there. Do you understand what I am saying? So the second phase of the process then is bringing the materials into Europe to process. Again you have to go through the same kind of silos, storage at the processors, and you go through cleaning and shelling and eventually processing. My colleague earlier mentioned you almost need parallel streams and one of our processors who is providing us with traditional materials is actually using a separate line, but, of course, that is very expensive. If you start to think about the total size of the soya crop, I believe it is 70 million tonnes in the US. Out of that 70 million only 1 per cent. is coming to the United Kingdom and out of that 1 per cent. I estimate that no more than 100,000 tonnes is segregated, non-GM material, because the rest is probably commingled. If you go back to 1968, when I

think there was just 2 per cent. of GM material, 1967, 15, 1968, 30, and it is suggested that it could be somewhere between 60 and 70 per cent. next year, so the need for segregation is not so much about GM, it is about the segregated crop.

Lord Wade of Chorlton

579. Just following up on that, it would appear to me that Spillers have identified a very interesting added-value marketplace for a small volume of specialist product. How much more do they actually charge for the specialist product?

(*Mr Morrison*) One of the questions was, are we seeing any cost benefits. The price for commingled material is no different from that of previous years pro rata, but the materials that we are buying are anywhere between 10 and 15 per cent. more expensive, so we are paying the premium for this system and we are taking from four different companies, so it is not just Spillers. But on top of that, we have very considerable expense in going out to these places and carrying out the traceability, the risk assessment, for the supply and also, of course, the further testing, and it was mentioned that it was £100 a test but you are into many tests.

580. What we are looking at here is a certain business opportunity. There will be a very small market of certain people who are so concerned about the issue of GM crops that they are prepared to pay a good more for the product. Would that be a proper way to sum it up? So it does not really matter whether you have added cost when you can get it back from the consumer, but that does not mean that the vast majority of consumers will be prepared to pay that extra cost.

(*Mr Morrison*) Herein lies the crux of the matter because we are putting all this time and effort in trying to establish this source of supply of the soya. I have only mentioned the soya here. At the moment we are not passing that cost on but clearly when we do yes, there will be a certain sector of the public that will be prepared to pay for it, and, of course, if they are not prepared to pay for it, then there will be no incentive for the likes of Spillers to supply or the likes of ourselves to produce.

Lord Moran

581. Are you and Spillers operating independently on this?

(*Mr Morrison*) Yes. I did say that they had set this up. In fact, they are only a small supplier to us and our main suppliers of segregated traditional crops are two other producers. I put this particular one up because they are the only company that I am aware of that has actually produced this marketing information.

582. On traceability, I think you have really, with your flow chart and your explanation of it, dealt with it. I do not know if you want to say any more about it. You have told us about the fact that there will be a cost and it is really a question of estimating the market. Are there precedents for traceability on other products?

¹ See supplementary memorandum.

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[Continued]

[Lord Moran Contd]

(Mr Morrison) Yes. Just to continue on this, there is an important aspect to this. You have seen the multiple steps and, although we have gone to these great lengths, as Mr Parry said, we have still ended up with some of these materials having up to 1.5 per cent. GM presence due to this adventitious contamination through the process. So we always have this at the back of our minds, that we have done all this but we cannot get better. So that is an unfortunate aspect of it. Yes, there are other traceability systems, obviously the organic traceability one, where I think their levels of acceptance can be, I think it is up to 4 per cent. of mix, and there are various other farm assured systems that supermarkets are operating these days, that retailers are operating, and on top of that, of course, there is now the beef passport system as well, which can set a precedent.

Chairman

583. Could we turn to labelling and could I ask you what your policy concerns on labelling are? Could I also ask you a specific question about assurance to consumers that GM foods are regulated. Might there be merit in a kitemark?. Is there any scope for something like that in the field of genetically modified foods?

(Mr Parry) My Lord Chairman, perhaps I could respond from three perspectives. UB's policy is certainly to label according to both British and EU laws and we supplement this with customer Careline services, where people can get more information on demand. However, as I referred to in my opening remarks, and Mr Morrison has also referred to subsequently, we firmly believe that if we do not differentiate a product which has been manufactured with traditional materials from a product prepared with GM ingredients but through whatever means is adventitiously contaminated, we do not allow the consumer any choice at all. That would be the net result, and this is why we believe that it is another reason why the industry itself urgently needs both the threshold and the *de minimis* level clarified. That is a fundamental issue and certainly it was referred to by the FDF in their submission earlier on. I would go further, to say that as a business we actually do not support negative labelling, i.e. GM-free, and there are two elements to it. One, we believe it would be misleading the consumer, as in our opinion it could potentially send the wrong message about genetic modification, but I think a more important element through the flow charts that Mr Morrison has referred to and the references which have been made earlier in both submissions today, is that substantiation of such a claim we practically believe to be unachievable, which is a fairly fundamental point but it is a perception and belief that we have.

584. And the kitemark?

(Mr Morrison) If you are not making a GM-free claim, which, as we said, we do not believe we can, then we cannot see the benefit of actually making a GM kitemark presence. I am not sure we would see any benefits for it across the business.

585. But then what does the issue of choice come down to if you cannot say a product is GM-free? What then is the choice that the consumer has?

(Mr Morrison) I think the key here is the threshold limits, which we really do need to have in place to take account of the low level of contamination that we talked about, because if we have to label across GM presence then the consumer has no choice at all but by setting this *de minimis* threshold level, then this immediately gives the consumer a choice.

586. But you are saying GM-free? Above that level it is GM-free?

(Mr Morrison) No, we are not saying GM-free. You are just not making a claim. So you either say there is GM presence, as per the legislation as it currently stands, or you are not saying anything at all, and we would advocate not saying anything at all for products below a threshold baseline.

(Mr Parry) But against clearly defined threshold and *de minimis* levels, which would then also substantiate and endorse the significant segregation and traceability that Mr Morrison referred to earlier on. So we believe that there is a distinction that can be drawn.

Lord Wade of Chorlton

587. The choice is between having a little bit or a lot and if you want a little bit you pay a lot of money for it?

(Mr Morrison) I guess that is quite true.

Lord Moran

588. Have you come under any pressure from wholesalers, supermarkets and those for whom you make goods, either for or against genetic modification?

(Miss Scott) Yes, we have come under quite a degree of pressure from a variety of sources. I think the Committee is very well aware of the stance on GM of certain supermarket chains and the direct impact that has on our business and that clearly, to respond to that, we have to do one of two things. We either have to source traditional traceable crop or we feel if we are to provide guarantees of "GM-free" status, then we will have to reformulate a particular ingredient such as soya out of our products. Clearly in terms of how that corresponds to our own company's position for our own branded goods, there is an important point here. Fortunately, we are currently in a similar position. Wherever possible for our own brands we are sourcing traditional traceable crops, but as I think I implied, the position and stance of retailers is obviously influencing very heavily what we are doing as manufacturers. Just to touch on some other pressures that we are also receiving, we are beginning to observe the involvement of local authorities influencing school canteen meals and tuckshop foods. There is a move potentially to exclude all GM ingredients from school canteens and from tuck shops. Indeed, we have heard from one wholesaler that provides canteens that they will no longer stock any branded product which contains GM as an ingredient. So as a manufacturer we are now

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being dictated to about what we can and cannot have in our products, and this is obviously an increasingly worrying concern to us.

Lord Jopling

589. Could I turn to the bioscience companies. Do you have any reservations about the way they conduct their affairs? Have you heard suggestions that they tend to go round the world developing their products in areas where there is the minimum of regulation, or—shall I put it this way—they are helpfully regulated? This Committee had a case of this some time ago, of genetically modified salmon which a company wanted to develop, was barred from doing it in America and so came to Scotland, of all places, where they were permitted to do it. Are you uneasy about the way in which these bioscience companies seem to go round the world finding easy places to carry out all sorts of experimentation?

(Miss Scott) Perhaps I can pick up a general point. Clearly we have no problem with biotechnology's involvement but what we object to strongly is the imposition of biotechnological advances on manufacturers and retailers like ourselves, and also clearly on consumers, without there having been proper, adequate consultation and review of the scientific evidence. Indeed, this is historical but our views have not been sought in the past and one might say that our views have even been trampled on by the fact that they have not been sought. I think we have mentioned before that the one non-negotiable aspect of our business is that our foods must be safe and they must be perceived as being safe by consumers, and we believe that consumer anxiety rises and is a difficulty to manage if we do not have an adequate framework and system to manage the introduction of new developments, and inform the public, as I indicated in one of my earlier responses, about new developments prior to products actually being on the shelf. So we feel that the lack of consultation, the lack of notice, the imposition of some of the past biotechnological advances, has not been helpful in gaining public acceptance. I have to say, regarding your specific question about biotechnological companies seeking favour from countries where the regulations might be more sympathetic, I personally do not have any knowledge of that, but my colleagues may have.

(Mr Parry) No.

590. Could I go back to what you said a few seconds ago. You said you had been "trampled on", I think were the words you used, by the bioscience companies. I think it is a terribly important point that you are making to the Committee. I wonder if we could have some examples, either now or in a paper that you might submit to us, of the way in which you feel you have been trampled on because I think this is important. But I am surprised that you do not have a view as a company with regard to the point I made about bioscience companies running round the world looking for easy places in which to do whatever they want to do?

(Miss Scott) I think rather than not having a view we are just not aware that that is taking place, but my

colleagues or others in the industry may be more familiar with that.

Lord Wade of Chorlton

591. Just to make sure that we know what everybody is talking about, what Lord Jopling is referring to is a company that wished to undertake trials on fish in containment. Having done that in the United Kingdom they did not wish, and would not have been allowed, to put the product into the environment. It was not that they found the system here any easier to get a product into the marketplace. So I would not want to give the impression that, in fact, our regulations allowed products to be introduced here that had not been introduced somewhere else; it was merely the testing. You do a lot of work also in China, do you not?

(Mr Parry) We do some but it is not particularly significant.

592. Do you produce products for the Chinese marketplace?

(Mr Parry) We do produce some, yes.

593. What is the reaction there of the consumer to these products?

(Miss Scott) We do not have detailed knowledge of consumer attitudes but certainly my role of communicating to the business is international and we do so on this issue. We are not aware of any significant, or any, feedback at all from that market, whereas we do pick up quite considerable differences of public attitudes and opinion right across our European markets.

594. So what you are referring to is the different views of public consumer opinion in different parts of the world when you are referring to other issues?

(Miss Scott) Yes.

595. Which are very different?

(Miss Scott) Absolutely.

596. In the United States of America there is an enormous consumer acceptance of this technology, as there obviously is in China. You have never heard of anybody from there, whereas it is just in Europe that there is a particular concern?

(Miss Scott) Indeed.

(Mr Morrison) Could I add a further point. Our regulations, of course, do cover the aspects that you are talking about, so even if research is undertaken with agreement to do that under 90/220, if the licensing is approved to do the initial work and then it is not allowed to be released, does that not really show that the system is actually working?

Lord Wade of Chorlton: Exactly.

Lord Jopling

597. With great respect, no, especially if the initial work is done in a country where there is virtually no legislation or monitoring, and I think there are countries where that is the case.

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(Mr Morrison) As I understand the legislation—and we are not directly involved in it—

598. Sorry, I am not talking about the United Kingdom. I am talking about other countries around the world which have virtually no regulation whatever.

(Mr Morrison) All we can come back to then is the fact that we do need, on an international basis, a body to advise, to regulate. Mr Ferguson referred to an overarching body earlier and was really saying that that overarching body needs to be international rather than United Kingdom-based or EU-based, but I certainly think that what we have here seems to be working quite well and we would like to see it extended.

599. Just to finish this, coming back to the “trampled on” point, can we receive a paper from you on what you had in mind when you said you had been extremely irritated to have been trampled on by various bioscience companies?

(Miss Scott) I think we were really citing the introduction of the commodity crops. I am not sure that there are details that would elaborate more than the general perception of the food industry in the United Kingdom and across Europe, which was that, although we are in discussions, as colleagues at FDF have said, through trade bodies and so on, largely the introduction of the US commodity crops into the United Kingdom and into Europe was not debated and discussed in detail in advance and, therefore, the public in general in the United Kingdom and Europe did not have the opportunity, as I said, of properly debating and discussing the introduction of, and developing, an appropriate system of managing the introduction of the particular commodity crops into these countries. So I think it was a general comment that I was making rather than more specific detailed comments.

(Mr Morrison) Could I add one point to that. As we have explained about the traceability and the great lengths that we have gone to, I think that actually reflects the problems we have in being able to have a product that we did not need to label because we could not do it directly because of the commingling issues on soya and possibly as well on the maize.

Chairman

600. Would you go so far as to say that the lack of any international agreement at the present time on the handling of GM crops is something that is causing you problems today, or if not today, is likely to in the near future?

(Mr Parry) Undoubtedly we believe that to be the case and I think that Mr Ferguson in his comments earlier on regarding the international overarching co-ordination amply described our feelings as well. So the answer to your question is undoubtedly, yes.

Lord Grantchester

601. As a company, are you involved in any work on a code of practice and, if so, with whom are you developing it? Are you involved in any way with a governmental body or a European body? If not, should they be involved?

(Mr Morrison) We are not directly involved, no. Obviously we were very much involved in the development of the IGD guidelines but we are not involved further. We are aware of the NFU initiative but if there were to be any guidelines, then I think they need to be on a much wider scale than just the United Kingdom because most of these GM crops are likely to come from abroad in the near future.

Chairman

602. Are the delays involved in the processing of applications for the release of genetically modified products within the European Union's regulatory system also something that causes you concern or problems?

(Mr Morrison) Of course, that is further down the chain than we are but we are aware that there is concern about the length of time that they do take to be approved. If it is a United Kingdom one, it would have to go through the United Kingdom process and then that would have to go to the European Union as well and perhaps it may be better to have a—we keep talking about overarching but an overarching European Union protocol, but very much based on the United Kingdom system because that one seems to be working quite effectively.

Chairman: This overarching committee is going to have an awful lot to do. That brings us to the end of our questions, so perhaps I can thank you all very much indeed for having come to give us evidence. It has been extremely helpful and interesting.

WEDNESDAY 21 OCTOBER 1998

Present:

Gallacher, L
 Gisborough, L
 Grantchester, L
 Jopling, L

Rathcavan, L
 Reay, L (Chairman)
 Wade of Chorlton, L
 Willoughby de Broke, L

Clanwilliam, E.

Tordoff, L.

Examination of witnesses

THE RT HON. MICHAEL MEACHER MP, Minister for the Environment, Department of the Environment, Transport and the Regions and MR JEFFREY ROOKER MP, Minister of State, Ministry of Agriculture, Fisheries and Food, called in and examined.

Chairman

603. Good morning, Ministers. It is very rare for a Lords Committee to have appearing before it at the same time two Ministers of the Government, but I think on this occasion, in view of the overlapping responsibilities of your two Departments, it is entirely appropriate that this should be the case and I would like to thank you both for having decided to come to help us in our inquiry into genetic modification. I believe that you would both like to start the proceedings by making short statements, so perhaps I can invite you now to do so.

(*Mr Rooker*) Thank you very much, my Lord Chairman. Can I first apologise, by the way, for the absence in the room of my colleague Lord Donoughue, who indicated to me that he would normally have been here, but, as you realise, he is recovering from his recent operation. I just want to make a very brief statement about MAFF's approach to the control of GMOs. Public health and the protection of the environment are this Government's first priority on GMOs. I want to make it absolutely clear that we shall apply all the relevant legislation, that on GM foods and GM crops, where we share responsibility with the Department of Health and DETR respectively, plus that on seeds and pesticides, where MAFF takes the lead, fully and rigorously. Applications relating to GMOs will be dealt with fairly and they will not be given any preferential treatment. We need to recognise, however, that GM crops are now being grown in considerable quantities in other countries and that the UK's policy towards their use, and that of their products, must be based on a clear analysis of the scientific facts so that it is capable of being fully defended in international fora. In addition to the statutory requirements, MAFF has been considering what further safeguards need to be introduced to respond to the concerns that organisations and members of the public have expressed about the possible impact of GM crops when grown commercially. I should add that Ministers are not immune from these concerns. I am aware of concerns that herbicide tolerance, which is one of the main traits being engineered into crops for use in the UK, may cause serious problems as a result of their spreading to neighbouring crops and related wild plants. The best way to avoid such problems is for extra care to be

taken when the crops are grown on the farm. MAFF has, therefore, urged the proponents of GM crops to draw up guidelines on their correct use, on proper identification and on full record-keeping. The industry group, known as SCIMAC,¹ dealing with this has made very good progress so far this year which we certainly welcome, but we are pressing them further to implement measures to secure compliance with the guidelines and of course proper sanctions if they are breached and not until we are fully satisfied will MAFF give our endorsement to this approach. It will be an industry code of practice, but once MAFF's imprimatur is on it, I know it will be read as a government code of practice, and we will not approve it until we are fully satisfied. There is also concern about the impact on biodiversity of the herbicides which would be applied to GM crops. The argument is that their use would interrupt the food supply chain for insects, small mammals and birds. There are differing views as to whether there would be environmental advantages or disadvantages in using a single, broad-spectrum herbicide compared with the current practice of using several different products. I have, therefore, asked the Pesticides Safety Directorate to prepare for me a scientific review comparing the likely impact on biodiversity of current and possible future practice. Some people have suggested that the level of herbicide usage on herbicide-tolerant crops will rise, while others have suggested it will fall. In order that we are properly informed on the point, I have also asked that the scientific review should include an analysis of the likely level of herbicide usage. A prior review of this kind should be able to make useful forecasts, but there is no substitute for monitoring the actual usage when the crops are eventually grown. I am asking my officials to discuss with the industry an enhancement of the Pesticide Usage Survey to give us specific information on this point. I am also ensuring that herbicides to be used on GM herbicide-tolerant crops will have to be specifically reassessed for this purpose. Their existing approval will not automatically be transferred to this new use. The assessment will cover their effect on non-target species. Lastly, there is the issue of the long-term safety of the products of these crops when used as foods. All GM foods are rigorously assessed

¹ Supply Chain Initiative on Modified Agricultural Crops.

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for safety by the Advisory Committee on Novel Foods and Processes, using internationally recognised procedures endorsed by the World Health Organisation, before being allowed on the market; this is not an operation behind closed doors. However, the Government is currently looking into the possibility of going even further by introducing monitoring arrangements capable of picking up any unexpected effects should they emerge in the future and I hope to be able to make an announcement about this very shortly. I hope, Chairman and Committee, that this demonstrates that in MAFF we are not rushing ahead, but thinking ahead on the control of GMOs. Our approach to these matters is of course an integral part of the Government's overall policy towards the use of biotechnology and, therefore, I very much welcome the announcement which is being made this morning as we meet of a new Cabinet committee under the chairmanship of my right honourable friend, Dr Cunningham, to oversee developments in this area. The terms of reference will be to consider issues relating to biotechnology, in particular those arising from the use of genetic modification. This will enable all of us to ensure the Government's policies in this very complex area continue to develop in a fully co-ordinated way. I hope the Committee find that statement of use.

(Mr Meacher) Thank you very much, my Lord Chairman. I also would like to say that I am grateful for the opportunity to make a brief opening statement to highlight in effect three issues in what is, I think, a pretty fast-moving debate. Firstly, as to the negotiations on the amendment of Directive 90/220/EEC, the UK welcomed the Commission's proposal which we think helps to address some outstanding issues, but we think it can go rather further. Our aim is to strike the right balance between protecting the environment and human health, on the one hand, and, on the other, maintaining the proper degree of certainty needed by business for the development of new products. I think it is right, as my colleague has said, that we should be cautious at this relatively early stage of the large-scale use of the technology in the environment and to make sure that for every product, we have practical evidence on safety before we take a decision on whether to move to commercialisation. For these reasons, the UK is seeking to make sure that the scope of the Directive and of the environmental risk assessment is well defined and broad enough to cover indirect as well as direct effects of GMOs. We want to strengthen the links between this Directive and EC product legislation, such as the Novel Foods Regulation, and we are strongly promoting the introduction of mandatory monitoring of the effects of products in use following market approval. We shall also press for changes to ensure that Member States' views are effectively reflected in any decisions on the marketing of products. I think this is crucial in making the best possible judgment on safety and, not to be underestimated, it will also help the acceptance of the technology. Now, to make the regulatory process predictable, we are looking for sensible, but defined time-frames for each of the steps in the

decision-making process. We have also pressed for maximum disclosure of information and supported consideration of ethical issues at the Community level. I think there is considerable support for these ideas and we are hopeful that when the amendment finally comes into force, we shall have an improved regulatory regime, but we certainly must not pin everything on that because it will be a number of years before the amendment is agreed and comes into force. At the same time, we are not despondent; I think there is much that we can do now, even within the framework of the present Directive, and, if I could put it like this, we are trying to exploit every opportunity for improved controls and open debate. Secondly, in addition to the important work on revising the Directive, I have been considering how best to respond to calls from groups, such as English Nature, for a moratorium on the commercial release of certain GM crops and of course to the great public anxiety that undoubtedly exists which surrounds this whole technology. The concerns of English Nature and others centre largely on fears that the widespread planting of GM herbicide-tolerant crops may lead to changes in agricultural practice that will reduce our already declining biodiversity, and I feel strongly that the commercial use of GM crops in agriculture must not put unacceptable pressure on our countryside and our wildlife and prejudice our goal of maintaining and, if possible, wherever possible, enhancing farmland biodiversity. I am, therefore, very pleased to be able to announce this morning that we have reached agreement in principle with the plant breeding industry for a programme of managed development of herbicide-tolerant GM crops whereby the first farm-scale plantings are strictly limited and monitored for ecological effects along with comparable plantings of conventional crops. This process will be underpinned by the strict guidelines for best practice in using GM crops which my colleague, Jeff Rooker, has already referred to. The results of these farm-scale evaluations will be carefully assessed before we move further. I feel it is extremely important that we do not travel further down the road to commercialisation of GM crops before we have this information. If, during this process, we do find evidence of harm, then we can take appropriate action. The industry has also made the important commitment that no insect-resistant GM crops will be introduced into the UK for the next three years. The concept of managed development, I believe, provides a precautionary way forward to investigate in a proper scientific framework the concerns that some GM crops might be harmful to the environment. Thirdly and briefly, my Lord Chairman, I also welcome the announcement that Jeff Rooker has referred to of a new Cabinet committee today. I am acutely aware of the public unease over genetic modification and the widely-held belief that these concerns are not being heard or addressed by the Government, however inaccurate that actually is. In my own area of responsibility, I am also aware of the need to look at developments on a generic level in order to take a more strategic approach and ensure that the wider issues are addressed properly. Many on both sides of the debate have proposed an environmental

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stakeholders' forum to discuss and advise on environmental issues raised by biotechnology. Such a forum might include representatives of everyone with an interest, such as farmers, plant breeders, conservation bodies and public interest groups. This group would work in parallel with ACRE, which would remain a scientifically-based committee, considering applications to release or market genetically-modified plants and other organisms on a case-by-case basis. Obviously, my Lord Chairman, I would be happy to elaborate on any or all of these issues in response to your questions. Thank you very much.

Chairman: Those were two statements of considerable significance and I would like to thank you both for having shown us the courtesy of first making them in this Committee. They raise several matters that we would like to pursue further in our questions.

Lord Gallacher

604. Ministers, do you consider that the technology of genetic modification holds potential net benefits for farmers, consumers and the environment and that, with appropriate safeguards, it should be allowed to proceed?

(Mr Meacher) As I indicated, we do believe it is right to proceed, but certainly with caution because there is a great deal of uncertainty about GM crops, particularly, as we have indicated, about indirect and cumulative effects on the environment and biodiversity and, for example, in regard to the transgenic outcrossing to related species. Now, as I have said, our own statutory conservation adviser, English Nature, has called for a three to five-year moratorium on the introduction into commercial agriculture of herbicide-tolerant crops and insect-resistant GM crops. Now, this, as I said, is because of their concern about changes in agricultural practice which could arise and the possible knock-on effects of what I think we are all concerned about, the dramatic decline in farmland wildlife. English Nature has been joined in this by a number of other organisations, mainly in the NGO community. Now, we do believe that there is the need for a further breathing space to allow additional systematic research to be undertaken in controlled conditions and it is for those reasons that I have been very pleased to announce that we have reached this agreement in principle both with English Nature and with the plant breeding industry to shift from the current field trials on a very small scale, like we have at the moment, to farm-scale plantings under carefully controlled conditions, and I underline those words, underpinned by the strict guidelines for best practice use of GM crops which have been developed by SCIMAC which we attach great importance to, the industry body of course representing farmers, the seed trade and the biotech companies, because it is only, in our view, on this basis that further research data which we believe is required, and I think that is widely accepted, can then be systematically compiled. Of course we have at the moment not any commercial growing of GM crops and we believe that this wider testing or, the phrase which I used which I think is a

good one, managed development must now be completed before we are in a position, as I say, to reach a decision on whether or not to proceed to commercial planting in this country. So the answer to your question, rather a long one, is yes, we do think that there is merit in proceeding further, but on a larger scale with very careful control of the conditions in which this is undertaken before we reach a final decision.

(Mr Rooker) I wonder if I could just add a point about the consumer on that because I think there are potential net benefits to the consumer and the Government's first priority is the protection of the consumer in relation to health in respect of food, and of course the environment, as Michael Meacher has made clear. From the industry's point of view, to make sure the consumers see there is a net benefit, they will have themselves to convince consumers that there is a net benefit for consumers as well as producers. It is not sufficient for the industry to make the point that all the benefits, the ones they emphasise, tend to be for the producers, so the consumers need to know that there are some benefits for themselves, they need to know that the process of control, checking and assessment is open, transparent and as universal as possible, and the consumers need to be given choice. Now, that being so, the net benefits can be put across to the consumers in a much more consumer-friendly way than they have been hitherto put by the industry. It is very early days in this at the moment.

Chairman

605. Could I ask a question on the farm-scale plantings, Mr Meacher, which you announced in your statement? My question is, under existing European law, will they count as a trial release or a commercial release? Will they require that there has been permission to release commercially at EU level before they can take place or not? What will happen to the crop after harvesting? May it be sold?

(Mr Meacher) They will be covered of course by the current 90/220 Directive and because the completion of the amendment of that Directive is going to take some time, they would then be regarded as trial, not commercial, plantings.¹ An awful lot does depend of course on the SCIMAC code which has been developed and I think we have reason to be confident in it. I know a great deal of negotiation has gone into this. It is finalising a code of practice and guidelines for newly-developed herbicide-tolerant crops. That will provide for what we are now envisaging, a framework for monitoring and control at and between each stage of the primary supply chain and a series of formal obligations subject to independent audit stretching from the initial supply right through to final sale and despatch of the harvested crops and specifying detailed on-farm

¹ The Minister adds: all the proposed farm-scale plantings will be covered by a deliberate release consent under directive 90/220. These will either be for trial releases (directive 90/220, part B) issued by UK Competent Authority or a commercial release (directive 90/220 part C) issued by another EU member state.

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management techniques and guidelines to ensure best practice, as we have been saying, in the best use of these crops. That includes, and perhaps I could just spell it out because I do think it is very important in terms of public confidence to understand the depth and comprehensiveness of what we are now proposing, that includes the separation distances between GM and non-GM crops as they are growing in the field, the segregation of GM and non-GM crops in cultivation, in harvest and through the whole supply chain, the full labelling of harvested crops, on-farm inspection by the British Society of Plant Breeders as well as independent auditors, and the monitoring and strict control of follow-on crops. We believe that that is a very comprehensive and detailed framework in which we have confidence and we believe the public should have confidence.

Lord Grantchester

606. If I can ask a supplementary at this early stage, we have heard recently, especially in relation to BSE, that Ministers make decisions to proceed only according to the best scientific advice available. Could you please confirm or comment on how far this may apply to GM foods?

(*Mr Meacher*) Well, obviously Ministers can only take decisions on the basis of the best scientific evidence available. There is no other alternative way to proceed and obviously that is how we shall proceed and it certainly applies in the case of GM crops, and of course we are taking account not only of an ongoing programme of research, which is very substantial, in this country, but also of research which is being undertaken elsewhere. We are keeping a careful monitor of all of that work and we will of course look to any new and, at this stage, unpredicted research findings in terms of deciding whether any decisions that we have taken do need to be modified.

(*Mr Rooker*) If I may say, that is one of the reasons for the setting up of the Cabinet sub-committee so that we have got real, joined-up government on this issue because it covers at least four different departments in addition to the ones I have mentioned this morning. Naturally, the best scientific advice, and I attended a meeting of the Tyndall Forum last night with 100 scientists discussing GMs and they did not all agree with each other, and I fully accept that, but one does not expect that, but as long as the advice is from a broad spectrum and we are open and transparent about it so that we can receive, if you like, contradictory advice, that we can debate the issues in the international fora as well, this is not an issue, like I think when you started your question, where it has been done behind closed doors, but we have been very open and transparent about this, so there will be no argument about people with alternative views not being able to put them and having them widely known to Ministers.

Lord Tordoff

607. I would just like to follow that up because the Select Committee has had problems in the past with Directives coming from Brussels which have been

based on very poor scientific evidence. The Bathing Water Directive and the Drinking Water Directive came in for considerable criticism from Sub-Committee C in the shape of Lord Lewis of Newnham who is a past President of the Royal Society of Chemistry and ought to be listened to. I want to test how robust you think your own advisory committees are in the advice that they supply to you and whether there are any gaps that need to be sorted out.

(*Mr Meacher*) Well, since, I think it is, February 1993, ACRE, the Advisory Committee on Releases to the Environment, has been offering us, as you know, expert advice on more than 160 applications to release GMOs. I believe that that work has been rigorously undertaken. I am aware, though, and perhaps this is what you are referring to, that there is criticism that ACRE's remit has been too narrow. Indeed, I believe that that is the case. Under the current regulatory framework, ACRE offers advice on the direct impact of GMOs on both the environment and on human health and there are many people who argue, and I think we are sympathetic to this view, that the indirect impact of GMOs should also be considered, for example, changes in agricultural practice and the subsequent effects on biodiversity, and it is because I am sympathetic to that that we are looking to extend the remit of ACRE. For example, I would propose that additional specialisms or expertise be added in terms of agronomic practice, ecology and farmland diversity. Those are criticisms, I have to say, not of the Committee, as such, but of the framework in which it has hitherto acted. We would like to extend that; we believe that that is what the public wishes and we believe that there is a good argument for doing that.

(*Mr Rooker*) May I just say on the food side because the advisory committees work both ways that the Advisory Committee on Novel Foods and Processes, and I understand earlier on you took evidence from Professor Burke, the former Chairman of that Committee, and I think later you will be seeing Dr Bainbridge, the present Chairman of the Committee, that is an expert scientific committee that has got a very wide remit. It publishes its agenda, its minutes and it has had at least one open meeting on discussing the monitoring, how we can set up monitoring long term once these foods are in the food chain on a large scale. Of course we have the advantage in MAFF, unlike in DETR at the present time, of having the Food Advisory Committee which is not a scientific committee, but which has a very wide remit also to take advice from the Advisory Committee on Novel Foods, so there is a second overarching look at the issue. There is cross-membership of the committees and, with ACRE and the Advisory Committee on Novel Foods, there is the Committee on Toxicity and the Committee on the Medical Aspects of Food Policy. So far as MAFF is concerned, we have consumer representatives on them all and the Novel Foods Committee also has an ethicist, a specialist, and always has had of course. Therefore, I am confident that that side of the operation as far as the food end of the chain is concerned is fairly robust and even more so now

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because of the announcement about the Whitehall side of it as well.

Lord Wade of Chorlton

608. Good morning, Ministers. I would like to turn to the question of what measures you are considering to deal with the possible, but not altogether proven, as you have admitted in your opening remarks, indirect and cumulative environmental effects which are at present not covered by the risk assessment process. You have since, Minister, reported in your opening statement that you might consider a stakeholders' forum which may be part of this process. The Royal Society also produced a statement recently which, though supporting the development of the technology, felt that there is a need for an overarching authority, as they described it. I would just like to press you a bit further on how such an organisation might actually work in practice.

(*Mr Meacher*) We are seeking to include consideration of indirect and cumulative effects in the drafting of the new Directive. It is of course the case that in the present Directive, 90/220, there are no details with regard to the approach to risk assessment, so we do welcome the annex on risk assessment which is included in the new Directive. It is, however, fair to say that cumulative effects are already addressed in the current regime because subsequent applications for similar products would take account of those products which are already used, for example, herbicide-tolerant crops, but we do believe, and I take your point, that this should be made more explicit in the new Directive and that is certainly the line we are taking in the working group in Brussels. Now, you mentioned whether there should be an additional advisory committee. We have given a good deal of thought to that and we do think that there could well be merit in that idea. I do think it is right that ACRE should remain an explicitly scientific and technical committee, whilst extending its remit in the way I have indicated, for example, by bringing in additional ecologists, but we would envisage and, as I say, there has been a lot of pressure from both sides of the argument to do this, but we would envisage an additional committee would include representatives of all stakeholders, and one is thinking of farmers, of the plant breeders, the conservation bodies and other public interest bodies, like the NGOs, and I think it has the very substantial benefit that it would engage in a public debate in a way that we have not done up to the present time. One of the factors I do find galling in government is that there has been a great deal of activity on this issue going on behind the scenes and it has not, I think, up to now been sufficiently understood and the more that that can be put in the public domain and that this can become a debate between the protagonists on both sides, I think the more confidence the public will have in the conclusions we reach, so I do think there is considerable merit and we are looking to proceed with the idea.

Chairman

609. So this would be a parallel committee rather than an overarching committee?

(*Mr Meacher*) It would indeed be a parallel committee. When you talk about an overarching committee, and this is another matter we are giving thought to, in the National Biotechnology Conference, which took place in March of last year, one of the recommendations arising from that conference of again a range of experts on all sides of the argument was that we needed what I think they called a "Warnock-style" commission to examine the ethical issues that arise from the advances in the technology. That is again something that we are examining and of course there is a proposal in the amended Directive that equally there should be committees to whom ethical questions should be addressed.

Lord Wade of Chorlton

610. Will the responsibility continue to lie with the existing Committees strengthened, with the new forum as an advisory forum looking at wider issues? Or would the responsibility for release be moved to a wider-based committee, or is this something that still needs to be decided?

(*Mr Meacher*) These committees are not hierarchical in the sense one is more important than the other; they have different functions and there would, therefore, still be the requirement for ACRE to undertake systematic scientific and technical assessment both in terms of human health and in terms of the impact on the environment, and the Government will not proceed unless such a positive assessment is made. However, quite separate from that, I think the broader issues as we move, as I say, through this process of managed development do need to be brought out in the public domain and I think that is probably the single most important missing dimension in the debate which we have had so far, and we look to bringing public opinion along. Whatever the conclusions are, the gap between public opinion and what many of the experts in industry are saying is now very large and that has got to be closed and that is what we look to this Committee to help us with.

Lord Rathcavan

611. Ministers, you have both referred to monitoring. Could you perhaps elaborate on how monitoring responsibilities might be allocated, particularly on commercial releases?

(*Mr Rooker*) Well, on commercial releases, I think it would be best if Michael¹ deals with that. I was referring to the food in the food chain because there has to be monitoring there, in my view. I have made it quite clear from my early days that I would not be comfortable with this new technology even though an open, rigorous assessment and approval of the products as safe for people to eat as consumers as required by the law had been fully gone through if we simply

¹ Mr Meacher.

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regulated, assessed them, approved them and then walked away and never did any checking, and I said in the early days that I want to have some system, difficult though it may be to construct, so that we have long-term monitoring of the use and the production and the consumption of these foods. Now, the human diet of course is extremely varied, as all the vast reports show and as we know from our own personal experience, and the Advisory Committee on Novel Foods addressed this earlier in the year and held an open meeting as to how such a monitoring and long-term surveillance programme could be constructed. They are due to repeat that hopefully before the end of the year. There is a lot of work being done and we are talking to the supermarkets, we are talking to the people who know. I do not know the details because it is early days for it to come to Ministers, but, for example, the big supermarkets, they know what everyone buys because they flooded the country with their loyalty cards. People may not think they are buying their points, but the supermarkets are buying information about what people buy. Now, we have to find avenues through health, surveillance and all other possibilities, and we are looking for anything that is unexpected and because you are looking for the unexpected, you have got to operate on a fairly wide, multi-faceted basis, if you like, without of course forcibly taking samples from people to do surveillance. This is something that the Advisory Committee is looking at with outside advisers and having open discussions about so that we can have comfort to give both to Ministers and consumers that the Government is looking at this on a continuous basis, not simply approving the products and then walking away from it. They have to know. People might argue about the nanny state, but people want the comfort of knowing that the Government and the regulatory authorities are looking at this on a long-term basis.

(*Mr Meacher*) Can I just add to that because we are working in tandem and there is another aspect of this. I think monitoring is an extremely important advance on the present position. The current Directive does not require monitoring after a marketing consent has been issued, but the new proposal in the Directive is to require notifiers to supply a detailed monitoring plan and we believe that however detailed this is as regards scientific evidence that there are no adverse effects of a product, we still need to carry out actual field observations in order to confirm that that is actually the case and there should also be means whereby any unexpected adverse effects, to which Jeff was referring, are fed back both to the consent holder and to the competent authority. We think that that is enforceable because monitoring will be a statutory requirement and we can, therefore, enforce it by requiring regular reports of outcome monitoring and after there has been independent scrutiny of those reports, then the competent authority can make its own decision about whether the monitoring does need to be improved, whether particular observations do need to be followed up if something unpredictable has been found, or whether the conditions of consent do need to be amended, and of course we can also enforce it, we can enforce the conditions of the marketing consent

through the work of HSE inspectors. So the Government does support the amended Directive to incorporate the requirements for monitoring commercial releases and these would have to be set out with each marketing consent and enforced by the relevant competent authority.

Lord Grantchester

612. I have heard it commented that the farmer is the best person to do this post-release monitoring and others have said that no, it is the biotechnology companies that should do the monitoring. Can you make some comments as to who you think is the best person not only to get accurate results, but that the public will have confidence in?

(*Mr Meacher*) Of course that is absolutely correct in that one is the cost of it and second is the public confidence in the results. In terms of cost, we think the financial responsibility for monitoring should lie with the consent applicant or the consent holder. It is then up to that person to decide whether to do it themselves or through some independent organisation, but, to take up the point that you are making, we envisage reviewing the proposed monitoring during the approval process to ensure that the methodology is adequate before a consent is granted, so whatever the person decides as the means of monitoring, he would have to get approval of that methodology before the consent is granted.

Lord Jopling

613. Can I begin, Ministers, by saying that I very much welcome the announcements you have made this morning which recognise that there is a need to restore public confidence on these matters and that you have between you, as I understand it, a general uneasiness about the regulatory situation as it is now and one which, I must say, I share. I wonder if you would be good enough just to summarise what is being proposed. You have mentioned the Cabinet committee and you have mentioned a possible environmental stakeholders' forum to discuss and advise on environmental issues raised by biotechnology. This would involve farmers, plant breeders, conservation bodies and public interest groups. I wonder if that is quite the same thing as the proposal which was put out recently by the Royal Society that "In addition, an overarching body or super-regulator should be commissioned by the Government to span departmental responsibility and have an ongoing role to monitor the wider issues associated with the development of GM plants". That seems to me to be a different matter from any environmental stakeholders' forum. I wonder if you could explain how you react to the Royal Society's proposal, especially as at the end of the paragraph in their statement, they say, "In addition, the new Food Standards Agency might have a role to play". I wonder if you could at this point tell us as much as you can about what is going to happen with regard to a Food Standards Agency, particularly as, as the Royal Society said, it could have a role.

(*Mr Meacher*) Well, could I start and then I am sure that Jeff will deal with the Food Standards

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Agency. I think we have a lot of sympathy with what is being proposed, that we do need some kind of overarching body which can monitor and control the technology to ensure that there is no damage to public health or the environment, and that is the overriding aim. Now, it is perfectly true that the stakeholders' forum, as has been proposed, did not meet that requirement. What I would say, though, is that the combination of all the measures that we are proposing does, I think, fully meet what the Royal Society is suggesting and let me take them in order. First of all, there is the Cabinet sub-committee which embraces all the departments who have a prime interest and, in no particular order, they are MAFF, DETR, Health and DTI as well as of course the Government's Chief Scientist and of course the territorial departments, and it is going to have a very wide spectrum of interest in ensuring co-ordination within government. Secondly, we are proposing to extend the remit of ACRE to take account, as I say, of wider ecological concerns which are not covered at the present time and that when we have had the opportunity next June because, by chance, there is going to have to be under Nolan Rules a major change in membership, we will ensure that those wider interests are brought in. Thirdly, there is the stakeholders' forum idea, if we proceed with that, which is designed to open the debate, which has, I think regrettably, up to now been too much behind closed doors, and to make sure that it is as transparent and as open as possible. Fourthly, and this is a matter on which we have not yet reached a decision, but we are certainly looking at what has been recommended to us by the National Biotechnology Conference, there is this "Warnock-style" commission, and I have always had great admiration, may I say, for Baroness Warnock and what she did in embryology and we are looking for that similar kind of body which is both learned and prestigious and takes a view that the public, I think, would have confidence in of the relationship between ethics and the rapid movement of science and technology in this area. When I add to that that SCIMAC is now bringing industry alongside what the Government is seeking, namely a slowing down of the process towards commercialisation until much fuller information is available, particularly on the environmental effects, I do think that the Royal Society ought to be, in my view, pretty satisfied because I think what they are seeking to do is now fully met by this range of different bodies and different remits.

(Mr Rooker) If I can just add to that, first of all, I have to say that I found the Royal Society document extremely useful recess reading and I make no bones about that and I think in due course, more particularly after today, it deserves and will receive a government response because it made very useful suggestions which I think do deserve serious consideration. I think by what we have said this morning, it will be seen that the Government in various guises has taken on board many of the points that have been raised, but it does deserve a response. So far as the Food Standards Agency is concerned, I want to make it absolutely clear that in due course the Agency will in fact become the UK competent authority for assessing the novel

food applications under the Novel Foods Regulations. In other words, the Advisory Committee on Novel Foods and the Food Advisory Committee will report to the Agency, not to MAFF, and let us make that absolutely clear. This is a serious organisation that is contemplated and, contrary to some of the fabrications in the weekend press, it remains a Government commitment. Nevertheless, in preparation for the Agency, we have made considerable changes within MAFF and in fact in June of last year, 1997, by setting up the Joint Food Standards and Safety Group which is a joint operation of approximately 300 staff, with 250 from MAFF and 50 from the Department of Health, and they are headquarters civil servants dealing with all these issues relating to food safety in its widest sense. They actually answer to one civil servant who happens to be coincidentally a DH civil servant who had been on secondment to MAFF for some time, but a very senior civil servant, and he reports both to myself and to our colleague, Tessa Jowell, the Minister for Public Health, so the embryonic functions of the Agency and the staff are actually in place in many ways. We have proceeded with considerable effort in the early part of this year in terms of the drafting of the legislation and we will consult, as we promised, in due course on the funding of the Agency because we made a specific commitment in the White Paper *Force of Change* to do that and we are at the final stage, if you like, of discussions in Whitehall on the draft of the consultation paper for that. So the Agency will actually take over many of the functions, the legalistic functions that MAFF currently carries out. It will be open and transparent, the members will be appointed fully and consistently with the Nolan Rules and it will have an educational remit as well in respect of speaking to the consumers and the public in a way that frankly I would not, neither would Michael, have dreamed to say, "I am a Minister; believe me"; it does not work. The very reasons for having the Agency as a Manifesto commitment of the Government remain today as they did then and, as I say, it will become the competent authority in the UK for the Novel Foods Regulations and of course it will have the additional effects of both education and information to consumers.

614. It would be helpful if you could give us the timescale for setting up the Food Standards Agency.

(Mr Rooker) Yes, I have no doubt it would be!

615. Are we talking about this year, next year, some time, maybe—

(Mr Rooker) Well, not some time never which is what you were about to say, Lord Jopling. No, it is a Manifesto commitment which will be delivered. As I say, we are not waiting for the Food Standards Agency to be set up. We have made considerable changes both in staff and the way we work and, I might add, the way the advisory committees operate. They all now, every single one, have lay people on them as representatives of consumer/public interests. They publish their agendas, their minutes and the people on the committees are fully entitled to speak to the press and to do interviews. They are committees of independent people, not so much independent

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committees, and we are encouraging them. I have visited every single one that services MAFF to explain that we want them to be open and transparent in the way they work. We have made a lot of changes in advance because we want the Agency to take over this ethos which is already there. In other words, we are not operating as old MAFF, but new MAFF, if I can put it that way, so that the Agency has that ethos imbued in it as we start. Now, we will be ready to publish draft legislation, which we are committed to doing anyway, and the Cabinet approved this last year, and we will put the draft legislation and the consultation paper on charging through a full parliamentary scrutiny process. We are not publishing the draft legislation as a PR exercise, but it is part of the consultation process. There will be either a joint or a special ad hoc committee set up to take evidence from Ministers, civil servants, outside bodies on the draft Bill and the funding consultation paper. I do not know when it will be published in terms of the draft form, but certainly it will be by the end or around the end of this year, and that will be open and in the public domain. I do not know what is in the Queen's Speech—indeed I only found out the date of the Queen's Speech in *The Guardian* this morning, so I cannot pre-empt that, I am afraid.

Lord Willoughby de Broke

616. Segregation—what is your attitude to segregation of GMO products from non-GMO products? Is this something that ought to be left to the market? Is the traceability of GM products either desirable or in fact practicable?

(*Mr Rooker*) I think the answer to all of those is yes. I think there should have been segregation. I do realise that when this team of Ministers came into office in May of last year it was actually too late to do anything about it effectively and we had missed the boat by about 18 months, I understand. I could not believe, given the power of the supermarkets in our food system in this country, that they had not got the clout to demand segregation, but then they all told me, "Well, we are such small players in terms of our American suppliers for soya". Then I discovered the small part of the food industry when I opened the Vegetarian Food Fair and I found small firms who said to me that they had got sources of GM-free soya, for example, and I said, "Well, if you can do it, why can't the big players?" We held a meeting in MAFF earlier this year, January I think it was, when we pulled all these people together from the small specialist food chains to the British Retail Consortium, and we had a debate and we found it very interesting, Ministers and our officials, to listen to these different parts of the industry talk to each other. As a result of that, because our legal powers are very limited, we went away in MAFF and produced for the public and the food industry a list of originally 47 or 48, but it now stands at 59 company suppliers of non-GM soya which we have made available publicly and on the Internet, and we got this through the co-operation of the American Embassy, the Canadian Embassy and I think also the Dutch, and that will help in terms of people accessing

non-GM products. So far as the traceability is concerned, I think the technology is such that the laboratories I have visited, both MAFF laboratories and indeed the Laboratory of the Government Chemist which, unlike its name, is a private sector company now, have got the capacity for checking the claims that are made as to whether any of the ingredients are GM or not, and I emphasise "ingredients" rather than production process, and, therefore, the labelling of this, which people might criticise, but in terms of what is in the product they are buying to say whether it does contain or does not contain, needs to be checkable. Traceability throughout the food chain I think is important. I also say, and I say this knowing that I might tread on a few toes because the information I am about to say came to me not in my role as a Minister, but as a member of the public attending a public meeting in the Food Future Roadshow which went around the country recently, that the issue of tolerances of food supplies is very important as to whether a food is up to 1 per cent GM or whether it is totally because it is going to be very difficult in the future with bulk purchase and the transporting of these commodity crops around the world to make a guarantee that it is GM-free. It is going to be very difficult to do that. I was informed, as indeed were another 100 members of the public forum, that one of the big food producers, Nestlé, when supplying to one of the small food producers for its non-GM foods, has a tolerance level of 0.1 per cent to 1 per cent GM in its contract. That was delivered in a public forum and it did not come to me in any papers as a Minister. So saying a product is totally and utterly GM free is extremely difficult. The Americans understand nothing if they do not understand market forces. What they clearly do not understand is the desire of European consumers to know more about the way their food is produced and what is in it. The Americans may not be so concerned about that but European consumers are. I think the commercial pressure that can be put on the suppliers from America is such that in the end we may get a degree of segregation and traceability that they were not prepared to contemplate even 12 months ago. I would encourage consumers and others to apply market forces to segregation because what we are interested in as a government is not to push a particular technology. We do not wish our productive capacity to be damaged by not allowing our industry to participate, but above all we want consumers to be able to have a choice. They cannot really do that if you have got difficulties in the supply chain.

Lord Gisborough

617. Do you agree with the Commission that labelling for process is not desirable? Should labelling be required only for the food products of genetic modification, or for all products, for example, fabrics and bio-plastics?

(*Mr Rooker*) On that latter point, I have to say that is not an issue I suspect has been considered in MAFF other than when I saw a sweater that had been knit using the fleece of Dolly the sheep. That was a genetically modified fabric if ever there was one. So

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far as the labelling of food is concerned, I think at this point in time the emphasis has to be on the ingredients of the food the consumer buys because at the moment it does not include additives and flavourings. We are dealing with that so far as the UK is concerned because we are pressing the Commission to make sure that additives and flavourings that have been genetically modified can be covered in a labelling process. So far as the food production techniques are concerned, I have to say that that goes way beyond genetic modification. If we are to go down the road of labelling food products as to how they have been produced as opposed to what the ingredients are then I say that opens up a whole new ball game that goes way beyond genetic modification. The only issue I can think of which currently operates like this is the beef labelling scheme which is unique to beef and, subject to what those who are signed up to the scheme for their independent accreditation feel, they can issue the sex of the animal, the method of slaughter and that kind of thing as to whether it was religious or otherwise. I cannot see at the moment how I could possibly put a label on a product where refined oils have been borne out of genetic modification but of which there is no genetically modified ingredients. I think that would be very confusing to the consumer. It is still very early days for this new technology and I think it is best to stick to all the ingredients and we do need to cover the flavourings and additives issue as quickly as possible.

Lord Grantchester

618. Perhaps I could return to the issue of segregation. If we are going to achieve total segregation it will only be at the cost of duplicate facilities. Bearing in mind the fact that this is highly unlikely to happen, it behoves the EU to set some standards of testing and thresholds which I understand does not happen at the moment. Can you perhaps tell the Committee when or how you think this is going to be approached in the EU, i.e. a policy on testing and thresholds, and how can such a policy not become too burdensome on smaller manufacturers?

(*Mr Rooker*) The Government would be very unwise to set out on any course where it knowingly would damage small manufacturers. On the other hand, if small manufacturers are to enjoy the use of this modern technology, which has only been borne out of incredibly expensive research, the price they have to pay is to fully conform to the regulatory process. I do not think the fact that because a manufacturer is small means they can be accused of opting out of the regulatory process. The issue which I touched on earlier though of tolerances is important both for the small and the big players. This is under active consideration at the moment simply because of the millions of acres that are grown around the world now and it is going up by a very substantial amount and the commodity purchasing of the crops is going to make it extremely difficult, even with the best will in the world, for cleaning out containers and bulk carriers let alone food production lines, which of course is much easier to do. We are discussing our tolerance

levels. I do know that durum wheat regulation allows up to three per cent of other wheat in it and that is something that is accepted as the legitimate and it is still classed and no one argues that there is a fiddle going on or anything like that.

619. Do you have any timescale as to when there will be a policy and a standard set throughout the EU on this matter?

(*Mr Rooker*) No, I am not able to put a forecast on that. I went as far as I could with Lord Jopling on forecasting dates. It is actively being discussed in Brussels at the present time.

620. You are happy to confirm that nevertheless it is a very important matter that must be dealt with urgently?

(*Mr Rooker*) It is an extremely important matter which we are pushing. We are not prepared to accept that there is a settled view on this matter, that all these foods are the same. As we have indicated this morning, the consumer does not see it that way and neither do we as far as our role as regulators is concerned. There is a European distinctiveness to this issue which we are gradually sharing and encouraging our American cousins to embrace. I think it is very important that the European Union does act as one. It will not be possible for people to opt out of this issue within the Single Market as that would wreck the commercial advantages that are there for people.

Lord Gallacher

621. Are you concerned with the delays which currently result from the European Community's regulatory system? Does the revision of Directive 90/220/EEC address the problem in your view? If not, what changes are you seeking?

(*Mr Meacher*) I think there is a real issue here. I repeat again that our overriding concern is the safeguarding of human health and the protection of the environment and there must be no reduction in the thoroughness of scrutiny of applications, but I think we do have to accept that there have been some unjustifiably long delays at a number of stages. I think the Commission is partly responsible for this. What the Commission proposes for the amendment of 90/220 is that, firstly, there should be time limits introduced for nearly every stage of the process and as long as those are reasonable time limits and they do not bear on the need for the rigour of approval of applications then I think that is acceptable. Secondly, the clarification of the scope of the Directive and of the risk assessments should lead to fewer delays because implementation would then be less uneven across the EU. So on both those counts I think there will be an improvement under the new Directive. I do think the introduction of a reasonable timetable—and obviously that is controversial, we can have debates as to how long it should be—should solve these problems whilst still allow for the rigorous assessment of risks, that is the real objective, but there should not be undue procrastination either.

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622. Ministers, I think you have both mentioned the fact that views throughout the various European states are not the same. There is a different view within Europe compared to the United States on these matters. Although Mr Rooker referred to the fact that he felt there could be no opting out, if there were certain EU Member States who did not want to develop the technology as much as others it would be possible for certain countries to opt out and others to develop. Would this be politically practicable as well as physically practicable?

(Mr Rooker) It may be. The environmental conditions in different countries in the European Union vary and one would not expect all crops to be grown in all countries whether they are genetically modified or not and therefore I suspect it is going to be inevitable that within the European Union some countries will simply say, "We do not grow this crop as our environment is not suitable". I was struck, as I say, whilst attending the Tyndall Forum at the Royal Institute last night, by the stark contrast. In most of Europe we grow the food in the countryside. In America and Canada they do not, they grow the food in the vast prairies. Their countryside national parks are the size of our country; in other words, the two things are separate. In Europe we have to make sure that in growing food within the countryside environment we actually take care of issues that they are not required to take care of in the vast tracts of America and Canada. Within Europe itself we are all much of a muchness but the climate is different and there will be countries that do not grow crops. So far as people opting out for a political reason is concerned, I do not think that will work within the Single Market and I do not think that will be allowed. This is why I think it is important that we get as much consent and approval within Europe that we are all comfortable with as possible because otherwise it completely destroys the Single Market because the countries will not receive products made from those crops within the Single Market and that would lead to chaos and the break up of the Single Market. There could be environmental considerations where a country would say, "We cannot grow that crop in our environment".

Lord Rathcavan

623. Mr Meacher, the Community's scientific committees are to be brought into the approvals process. Are you content both with the provisions for their consultation and with the committees themselves, their membership and advice?

(Mr Meacher) There have been criticisms up to now. What the Commission is now proposing is that it be required to consult one or more of the EC scientific committees on any matter which is likely to affect human health or the environment before the decision procedure is initiated. I have to say that that goes considerably further than the current position where EU scientific committees have been used up to now to resolve marketing applications where there is no clear consensus amongst Member States. I suppose the obvious example is Novartis maize where Austria and

Luxembourg wish to impose a ban and this was challenged on scientific grounds and there was the use of the scientific committees to try to resolve that. I think what is important here is that the national scientific committees, in which we do have great confidence, continue to carry out environmental risk assessments and there is no question of transfer to EC scientific committees. However, there is the problem of exactly when an EC scientific committee should advise, i.e. what is the appropriate point of application of science? It is true that many Member States do take the view that the Commission should only consult scientific committees when the competent authorities object to marketing, which is basically the current position, or if they invoke the safeguard clause in Article 16 under the Directive. They also think that there should be fixed periods for consultation because there have been some unnecessary delays. These matters are still being discussed in Brussels and there is no final view, but certainly there is no question that scientific committees should continue to have a major role and they will be underpinned by what the national scientific committees are telling each of the Member States and we certainly think that that is the right foundation. The other point you raise, my Lord, is about the fact that there have been criticisms about the composition, about the appointment and about the accountability of these scientific committees. I know the entire system of EU scientific committees was subject to major reform last year. At least it is now the case that EC scientific experts are asked to disclose any interest. I think that is very important. It is certainly something that we are looking at ourselves in regard to our own scientific committee. There has not been a final resolution of the manner in which science should play a role but everyone agrees that it should play a role particularly where there are disputes and where the only way one can reach a conclusion is by taking the best scientific and technical advice available.

624. You referred to Novartis maize. As you know, they have got to plough up the Novartis maize that has been planted in France. How do you see this being resolved?

(Mr Meacher) Watch this space! The PGS (Plant Genetics System) hybrid oil seed rape is the first GM crop coming forward for commercialisation and the marketing consent has been granted. France was the country where an application was first made. I understand that the French, who have not issued a consent yet, may be expected to do so before long, but they are expected to take the view that there are grounds under Article 16 as to why there should be a derogation from France. All I can say is that we would be interested to see the grounds.

(Mr Rooker) During part of Michael's answer he may have given the impression that our scientific committees do not have full disclosure of interest. It is not something we are looking at, we do not need to. We not only have full disclosure of interest, they have to leave the room if the chairman considers the interest is so great. This is not something we have to be taught any lessons about by our European partners or the Americans in respect of being open and transparent

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about the people who will serve on our independent scientific committees. I want to make that absolutely clear because occasionally their integrity is challenged and attacked simply because they have their expertise borne out of working in industry for part of their life.

(*Mr Meacher*) The issue is how far there are grounds under Article 16 for a derogation. We ourselves have commissioned work from Dr Alan Gray at the Institute for Terrestrial Ecology in Dorset to look particularly at the impact on non-target species. We are expecting that work to be delivered to us some time next month and obviously we will look very carefully at it. He is doing a very thorough analysis of any grounds there might be in regard to this oilseed rape which would justify not implementing commercial growing, although I have to say that there has been agreement—and this is part of SCIMAC—that there will be no commercial growing of any GM crops for at least a year. The matter will be subject to further review as we move through this year. With regard to insect resistant GM crops, we have agreement through SCIMAC that there will be no planting of any such crops for at least three years.

Lord Tordoff

625. My Lord Chairman, perhaps I could just reinforce this point about the Commission's committees. I think the difficulty that we found in the past is in finding out who was producing this information. In many cases the whole thing was so opaque that you could not find out who the people were that were handing down the information or what the information was. In those cases it is impossible to have any peer review of the scientific findings. I hope that the fact that you have this underpinning of the national committees is going to help to prise out some of the mystery which lies behind Commission science.

(*Mr Meacher*) I absolutely accept that what is needed with regard to scientific advice is complete openness and transparency about the source, full revelation of the findings and the sources on which it is based so that it can be checked and verified by anyone.

Lord Jopling

626. Ministers, you have both repeatedly stressed this morning the importance of public consultation and transparency in the operation of the regulatory framework, but this has not prevented eco-terrorists from carrying out a number of attacks on trials. Will you confirm that the Government condemns those attacks? Do you think that the necessary scientific experiments can be carried out without excessively infringing transparency? Do you believe that steps need to be taken to deter eco-terrorism on the one hand but to allow these experiments to continue on the other?

(*Mr Meacher*) We are very concerned about this. There is undoubtedly, as everyone agrees, very real public concern about GM crops. In answer to your direct question, yes, of course the Government unequivocally condemn the unlawful destruction of GM field trials. These were not commercial crops, they

were field trials attacked by a small minority outside the democratic process. I think no one in a civilised and democratic society can do other than condemn it. It cannot be condoned. However, having said that, I think it is very important that we find a way to resolve the problem. I think one of the things driving these small groups is their belief that the Government either has washed its hands of it or is not doing sufficient, and that is why I think the right way to meet these concerns is to resolve the problem by opening up the decision-making process so that those who currently participate in violent means will have an alternative democratic avenue to argue their case and will be strongly encouraged to do so. I do think the proposed stakeholders' forum should help. It has been put to us, of course, that we should not reveal the location. The Directive does require that the location for these field trials should be stated on the application and it is posted on a public register. We have thought about this. I believe it would not be right to seek to withdraw from that openness and transparency. I think we should not be driven off this by a small minority of people. It is right that it should be open, although those who are responsible for these field trials can look to trying to find improved security for them, but I think the right way is not to fall back into secrecy, which I think would only encourage more misrepresentation and mischievous reporting, it is to remain open but to challenge them to come out into the open by providing a forum in which they can do so.

Lord Willoughby de Broke

627. Are you concerned by the degree of power which is being acquired over the process of producing GM foods by a very limited number of bio-sciences companies? If there is such abuse, how can that best be curbed?

(*Mr Rooker*) With the changes that have occurred in recent years there is bound to be concern that it is now a very small number of companies involved. I do not have the figures to hand but I know that the number of seed companies has drastically reduced in the last decade. The research and development costs of these products are very very high and it has to be appreciated that both the issues that Michael and I have referred to this morning are the result of maybe 20 years work in the laboratory and they have not just popped up out of nowhere. By and large you will only find large companies able to do this. We have now got very few companies, Novartis, DuPont, Agrevo, Monsanto and Zeneca. On the other hand, it is very unlikely that any one of those is going to dominate. They are going to be around for quite a few years. There is only a handful, it is true, but the issue is going to be one of competition and openness and operating a very rigorous regulatory system. They have got their own interests at heart and if they do not get it right the public will soon turn off them and this is why they need to look to their own operations to see whether they are seen to force the crops on the market earlier than there is going to be widespread public acceptance for them. As Michael has indicated this morning, there is obviously going to be some voluntary holding back.

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[Lord Willoughby de Broke *Contd*]

If they start—and we would encourage them—to give the consumers products that are beneficial to the consumers and not just themselves then I think that is very important, but it is in the end going to be competition and if they breach the rules we have got the power and authority to come down on them like a tonne of bricks. Some of these companies have breached consents. I am astonished that they would do that. They have done it because of slipshod management or whatever, but it is totally unacceptable. The sanctions under SCIMAC will be such that anyone who does not comply with the requirements will have access to the technology withdrawn from them. What we are proposing and what we are asking the industry to self-regulate is extremely powerful because we are going to be required to give our imprimatur to it. If people deviate and do not operate in an open and transparent way then they will suffer commercially in that respect, but at the end of the day our powers as members of the European Union, as members of the World Trade Organisation, are limited as an individual country, but we will do everything we can to make sure that the companies bring forward this new technology and all the research laboratories involved and not just the companies I have mentioned. There are many research laboratories working on this issue in this country. If they are in open competition and the competition is transparent and they do not reach a position where there is monopoly power then I am reasonably satisfied that we can have a degree of control.

Lord Rathcavan

628. The recent acquisition of PBI by Monsanto caused some concern. Do you think that these matters should now be referred to the Monopolies and Mergers Commission?

(*Mr Rooker*) That particular acquisition I do not think justified referral to the Monopolies Commission. I know that we had some advance warning of it as a matter of courtesy, there was no requirement to let us know about it, it had not got to that stage. I would have to take advice on this because references to the Monopolies Commission are quite specific. I have not received any advice to the effect that a Monopolies Commission inquiry into this area would be justified, but that does not mean to say that advice would never be forthcoming. This industry is not unique. In terms of the manufacturing industry as a whole, economies of scale and the control of unit costs, moving jobs and research around the planet to meet different conditions, whether it is labour or environmental, will happen on a constant basis. I think we have to keep a watching brief on it. We must not wake up one morning and realise, "Oh, there is only one company doing this any more." That would be a complete failure of the whole of the regulatory process. So we do need to keep a watch on it.

Lord Jopling

629. Minister, you said that the Government would come down like a tonne of bricks on a company who had transgressed the rules. Could you tell us

whether the same thing might happen to a company who tried to avoid the rules altogether? I do not know whether you saw a report recently of one of the big international companies beginning tests on genetically modified organisms in the former Soviet Union where there were virtually no rules and regulations whatsoever. We have had evidence in this Committee of a company who were denied the right to do certain experiments on salmon in North America and who then moved to Scotland to carry out that experiment. It all came to nothing, but that is neither here nor there. Would the Government be prepared to come down like a tonne of bricks on companies who started up activities in countries where there are no rules and regulations at all?

(*Mr Rooker*) We could not do it insofar as what they are doing in other countries. I do not know the particular details of this. This then requires international government cooperation. As I said in answer to the first question, our regulatory process on novel foods has been approved by the World Health Organisation. We are operating in international fora here. If companies are clearly seeking to get around the regulations so that those countries take a very hard line on the protection of the environment and safety of the public in relation to food then they are doing themselves massive commercial damage once this becomes known. I would imagine, without knowing the details, this is an issue that would have to be discussed government to government and internationally because quite clearly it is an unacceptable practice.

(*Mr Meacher*) Could I add a point about the international agreement on the movement of GMOs which has already arisen? I think this country has, to its credit, been in the forefront of trying to achieve the safe handling in the movement of GMOs and governments of both parties have long advocated an international framework for bio safety. I think there are really two main mechanisms to try and deliver this. You asked a question about enforceability and I think that is a good point and I think it is always difficult to enforce it into national agreements, but the actual agreements are there. It was the UK and the Netherlands that first developed the UN environment programme "International Technical Guidelines for Safety in Bio-technology". That sets down appropriate procedures for the safe handling of GMOs which is required under the Rio Convention on Biological Diversity. The problem, I repeat, is having an effective central enforcing mechanism for transgressors and I would be the first to admit that I do not think that exists at the moment. UNEP has been through a difficult phase. It is now resurrecting itself and it is looking for the enforcement of multi-lateral environmental agreements and agreements like the ones I have mentioned. The second is that the trans boundary movement of LMOs (Living Modified Organisms) is the focus of the bio-safety protocol under the Convention on Biological Diversity and we are committed in the negotiations—which are still on going at the present time, I think the last meeting is at Cartagena next February—to clear requirements at the global level for providing advanced information on

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safety to prospective importing countries because the problem is that many of those importing countries simply do not have the institutional capability to make the judgments that are necessary before importing. We believe that that information should be provided by the more advanced industrialised countries so that informed decisions can be taken. More needs to be done about enforcement and we do need to get agreement with regard to all countries on a bio safety protocol and I strongly believe that the British government's position is right on this.

Lord Wade of Chorlton

630. What we have opened up is a fascinating development of how things may happen in the future. Clearly, experience tells us that global agreements are not very easy to achieve. What would be a very serious matter is if we prevent, by over-regulation, development of this technology occurring in Europe. Mr Rooker sensibly made the point that the technology already is enormously expensive to develop and so the competition in the industry is not as we would see it in other industries where the entry costs are so much less. As we increase the entry cost through regulation we are driving the industry to become much more concentrated into very very large international organisations. They therefore have the choice to conduct research wherever it is easiest and cheapest for them to do it in the world. Is this an issue that we need to keep in mind? Clearly a global agreement might help to resolve the issue but that is not something that is going to happen in the immediate future. Do we have to be careful about keeping a balance, to allow companies to develop products under our regulations that they want to sell in Europe, lest people say, "Let's go and do it in Russia and China", and so slowly change the whole market system of these products? We would then have to buy them from places where there is no regulation.

(*Mr Rooker*) In the UK and within the Community at large we do have procedures for dealing with companies where there is market dominance that is against the public interest. If that was the situation then we have got procedures ourselves to deal with that. I think what you are touching on is almost what was mentioned in the previous question, i.e. if in terms of a breach of the regulations companies go elsewhere either to grow crops or to trial crops that we would not allow to be trialed, for example, because the situation is such that there are still plenty of things that are queuing up in the laboratory where it is too early, then that goes beyond the issue of market dominance. That is something that I think would require international agreement. If it is done for pure market dominance that then goes against the public interest then no amount of special pleading by these companies is going to be sufficient to get over that hurdle.

631. I was not suggesting that that might be the case. What I am suggesting is that if in Europe we make it more and more difficult for people to enter into the industry when there are easier opportunities for them to progress in other parts of the world Europe

could be at a disadvantage. It would not be in our interest for that to happen because we will have no control whatsoever on those products produced outside the EC. What I am saying is that, as regulators, we have to bear in mind that we want to keep a sensible balance by not making it too expensive for people to enter into the competition. Look at what has happened in the pharmaceutical industry. Quite rightly, we have had to introduce very large regulatory systems. The impact of that is to create very very large pharmaceutical companies because the cost of developing a new product is so high. I believe that we have to be aware of the possibility of doing that and make sure that we do not strike the wrong balance.

(*Mr Meacher*) I think it is a very good point that you make about competition. It certainly is the case that there is a steady increase in entry costs because it is a highly capital intensive technology because of the rising research costs which are involved and there is a major incentive to evade controls by going abroad. You talk about balance, but I do not think we can afford to reduce or undercut our own rigorous requirements. I think the real force of your question is that we have got to find a way of ensuring that these international regulations are put firmly in place and as quickly as possible and enforced. It is this enforcement problem that I find really problematic. The final meeting on the bio safety protocol is in about four or five months time. I hope that we can see that in operation next year.¹ If you are asking if I can be sure that in that timescale we have the mechanisms which can prevent evasion of those controls, I am not at all sure we have, but I think that is where we have got to place the effort, that is where we have got to ensure that those mechanisms are more fully in place and then monitor the regulations, how they are working and what further needs to be done.

Lord Grantchester

632. I want to ask about the differing standards governing the production of GM crops. What are you doing to satisfy the farmer who may find himself competing in the future against foreign produced food that is produced to different standards and with different controls to those which he is having to operate under in this country? Are you satisfied with the US regulatory process? What are you doing to secure wider international agreement concerning the handling and movement of GMOs?

(*Mr Rooker*) No one wants to impose any rules and conditions on our farmers and food producers that puts them at any disadvantage with international competitors. However, as we said in the White Paper on the Food Standards Agency, the protection of public health in relation to food is the number one priority. It is true, there are complaints from some of our producers which are that our welfare conditions are higher than their competitors', for example. That has been brought about by consumer pressure in this

¹ The Minister adds: although the final text is expected to be agreed next year the exact time of entry into force will depend on the number and timing of ratifications by member states.

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country sometimes with and sometimes without the Government's approval. I do not think we would knowingly go down the road of making life more difficult for our farmers. People have always asked about the Food Standards Agency and what it will do to stop foreign food coming in. The answer is nothing. We are in a Single Market as part of the European Union. The idea is that products move around the Single Market to everyone's advantage. Rules should be as common as possible within the Single Market and enforced in that Single Market. There are some areas where preferences vary on a regional basis and I think one has to live with that. It is not the intention to have a set of rules that put our farmers and food producers at any disadvantage be it in respect of animal welfare or in respect of the kinds of foods they can grow. We have emphasised very much today the efforts of SCIMAC when it comes to fruition. This is an industry-led operation. This is not something we as Government can legally enforce. We have gone as far as we can with the industry to get the industry to have self-enforcement and very tough regulation, as I think we have both indicated today, in order to win public acceptance and government approval for the code of practice. It cannot just be a piece of paper, it has to be much much firmer than that. I think that is the way we are going to have to go across Europe. I do not know any details of a SCIMAC operation in the rest of our European Union partners. We are in the very early days of this new technology. There is a hiccup with the French and the decisions of the French Parliament and we are waiting to see the outcome of that. We are not seeking to rush headlong into this new technology but we certainly do not want to do anything that causes over-regulation and puts our food producers at a disadvantage, but we are certainly going to regulate in the public interest.

633. Perhaps I could follow that up by asking you to answer the question on the US regulatory process which is different from this country and the EC. It does sound slightly illogical to ask our farmers to produce according to one standard and the consumer can go and buy of a lesser standard from the supermarket. It might come in through a lesser regulatory process that exists, for example, in the United States.

(Mr Rooker) We import into this country horticultural produce from 60 different countries, some of it with an extremely short shelf life. It is incumbent under the food safety legislation so far as the supplier of that is concerned to make sure that the food is safe. The European Union—and I emphasise this because we are not operating in isolation on this—has its own inspection process of checking third party sources. Recently they have been to one of the countries that supply meat into the European Union and they have got a six month warning to clean up their act in the abattoirs and cutting plants—and this happens to be a Commonwealth country. I am not convinced that the whole of the food chain is regulated like that. So far as the big players like the supermarkets are concerned, they are demanding far more traceability from all their suppliers about where the product is coming from than ever before. I know there are complaints by British

farmers about the different assurance schemes, but the supermarkets that are importing food into this country, exotic foods and foods out of season here, are doing everything they can because it is in their own interest to know as much about their supply chain as possible. Some of them, for example, refuse to buy on the opportunistic markets, they will only buy from the farms and the producers they have checked out in different countries. One of the leading brands, not one of the big five, said to me last week that from January on, when they have got the new rules about the welfare of pigs, for example, they will not buy their parma ham and their bacon and pork products from European countries unless their suppliers conform to the welfare standards that our people are going to have to conform to from January. I approve of that wholeheartedly and I hope more will do that because then our producers will be being treated exactly the same as people abroad whose foods we are going to buy.

Lord Jopling

634. Minister, I wanted to bring you back to Lord Grantchester's question about the regulations which apply in the United States. You said right at the beginning of this hearing with regard to soya bean that we had been 18 months too late and had missed the boat. To me, that implied a criticism of the way that the Americans have allowed the spread of genetically modified crops. There is a feeling around that there is complacency in the United States with regard to GMO regulation. At the same time, in Europe—and we have talked about France but they are not alone—Austria, Luxembourg and I guess Denmark are becoming more reserved and anxious about this. Your own evidence shows that the Government is becoming more anxious. First, do you think the Americans are too complacent and second do you see the danger of us running into a trade dispute with the United States over the course of the next ten years or so?

(Mr Rooker) On the first point, I think complacency is probably the wrong word. I think I highlighted earlier on the difference in where they grow their food. The vast prairies they have got means they are able to do things there without checking on all the issues that Michael referred to to do with the effect on the environment because it does not affect their "countryside" because that is elsewhere on a grand scale. For us it is different and so we have to look at it in a different way to the Americans. I do not say theirs is a complacent view. They have done their regulations to conform with their perceived risks to the environment, but their environment is not ours and we have to spell out to the companies in America that the European environment as well as the European consumer is different and has had a different culture to what happens in the States and as such they have got to take account of that. Whether or not—because we have got to do this within the European Union which gives us a degree of strength, if you like—that leads to a trade war, we certainly do not want a trade war with the United States, but there are issues that we have to disagree with the United States on in respect of discussions in the World Trade Organisation. We

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thought we had got a settlement on bananas but I understand they are still complaining about it. This is an issue where we do not want a trade dispute. There is an international forum in which to try and get these issues settled and that is what we have got to do. We cannot allow, taking the American example, the American environment and what has flowed from that in the way they have gone into genetically modified foods to translate to the European environment without us saying, "Hang on, we need different regulations because our environment is different, the way we grow our food is different." We have to demand those differences are taken into account, otherwise we are not fulfilling our duty for looking after both the consumer interest and the wider public interest and the environment.

(*Mr Meacher*) There is a very major difference in that I think it is something like 70 per cent of the UK is subject to cultivation. I think in the US it is less than ten per cent and that does have enormous implications in the handling of an issue like the GMO. I did speak to a very senior representative of Monsanto a week or ten days ago and I was struck by the degree to which I think he and his company are coming to terms with the fact that there is a very different culture within Europe and within the UK and that they have to accept that there can be, I believe, no question of using WTO rules just to ride roughshod over a very different

political and cultural landscape in Europe, but there has to be a slowing down of this process towards commercialisation, there has to be a meeting of all the reasonable research requirements and information and there has to be significantly greater acceptance by public opinion of GM foods before we can move towards commercialised growth in this country on any significant scale. I think that Monsanto, which is a lead company in this respect, has seriously begun to take that on board and I think the fact that they are partners in this programme of managed development means that they themselves have made commitments that they will not proceed to early commercialisation and the fact that we are going to review it before we reach any decision I think is a very healthy sign.

Chairman

635. Ministers, that brings us to the end of the questions that we wanted to put to you. Is there anything that either of you would like to add? (*Mr Meacher*) I think we have had an ample opportunity to say everything and a good deal more!

Chairman: I think we have had a very full session and I am extremely grateful to you both for coming before us and for being extremely interesting, patient and harmonious in your responses to our questions. Thank you very much indeed.

WEDNESDAY 28 OCTOBER 1998

Present:

Gallacher, L.
Gisborough, L.
Grantchester, L.
Jopling, L.
Moran, L.

Rathcavan, L.
Reay, L. (Chairman)
Redesdale, L.
Young of Old Scone, B.

Examination of witnesses

PROFESSOR PHILIP JAMES, Director and DR ANDREW CHESSON, Rowett Research Institute, Aberdeen, called in and examined.

Chairman

636. Can I welcome you both, Professor James and Dr Chesson, to this Committee and for coming to give us evidence on genetic modification. Thank you very much for having taken the trouble to come down from Aberdeen to help us in our inquiry. Could I perhaps start by asking you to introduce both yourselves and your Institute and say what your Institute does in this field and what your separate responsibilities are in the Institute?

(*Professor James*) Thank you. I am Professor Philip James. I am Director of the Rowett Research Institute, which is an institute predominantly funded by the Scottish Office and currently by the Department of Agriculture. This is an institute with 300 staff, but with visitors and students it goes up to about 400. We have a responsibility for essentially undertaking nutritional research throughout the food chain. We now describe it as a reverse food chain approach so that in relation to genetic modification of foods and plants we become involved because we are used to assessing industrial issues in relation to animal feed and we also have to consider increasingly the impact of agricultural developments through the food chain on human health. So we have both human studies and animal studies going together. I have other duties, of course, and I am asked to take part in UK Committees. Until recently I was a member of the Novel Foods Committee and I currently am still a member of the Committee on Medical Aspects of Food Policy of the Department of Health and am Chairman of the Nutritional Aspects of Novel Foods for COMA. I am also on the European Scientific Steering Committee, but perhaps we can come to that later. Dr Chesson is a senior member of staff with special responsibilities and perhaps he can introduce himself.

(*Dr Chesson*) I am responsible for the part of the research work in the Institute primarily concerned with events that occur in the digestive tract and the impact of foods, including novel foods and feeds on the events that occur within the digestive tract. In addition, I am a member of one of the scientific committees of the European Commission that operate out of DG XXIV, the DG that, as you will be aware, is concerned with consumer health and welfare. As a member of the Scientific Committee for Animal Nutrition (SCAN) I was seconded to a working group set up to look at all

genetically modified material which is being considered for release in Europe under Directive 90/220/EEC of the European Union. I am there to look primarily at the animal feed aspects, but clearly this is only one part of what the whole working group considers.

637. Thank you very much. We are extremely interested in your membership of the European advisory committees and many of the questions we want to ask relate to that. It will be helpful to us to hear about these matters ahead of a visit which we are making to Brussels next week. Could I start by referring to a matter which recently brought your Institute into the news, namely a *World in Action* programme which presented dangers concerning lectins in a potato and were purportedly based on data that was made available by your Institute. Could you explain exactly what happened in this case and why the misunderstanding arose, if that is what it was?

(*Professor James*) Thank you for the opportunity to make a brief comment on this. We regard this as a very unfortunate development because the Institute has been involved with a whole range of different analyses of GMOs and new developments in both the feed and food business. This particular issue of lectins is the interest of one of our most renowned scientists, Dr Pusztai, who for 35 years has been doing research on lectins, a natural constituent of plants with pest resisting properties and therefore of great interest to the plant breeding industry because of the natural attributes that lectins have. He has been studying the impact of these lectins in animals and man and has identified the fact that these lectins have varying effects depending upon their detailed structure. He alerted me about three years ago to the fact that he was becoming concerned that some of the lectins that might have been used were in fact those lectins which he already knew could have an impact on the animal gut and therefore presumably on the human gut. Of course some of these lectins that have been studied are very well known to us, for example in red beans that have to be boiled. You are boiling them before you eat them simply to destroy this lectin which otherwise has a major impact on the intestine. His concern was that with the joys of being able to identify a particular molecule with pesticide properties there is a tendency to say, "Ah, it will destroy the insect gut, let's put it

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[Continued]

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into a plant". That could be done without considering what the potential impact might be on other animals and indeed on man. As a result of this concern, which was published and which he has been discussing in scientific meetings over many years, I took the concern to the Novel Foods Committee in Britain when we were considering one of the plants being manipulated with a new insecticide insert. As a result of looking at the process whereby we assess novel foods we came to the conclusion that we needed an additional track so that we would have an early alert on the broader impact of some of these lectins. Therefore, the UK system for assessing novel foods already has that additional safeguard incorporated into the process as a result of Pusztai's concern. We also arranged for that to be in the European system. What happened with *World in Action* was that they heard of two or three of our programmes, one of which was funded by the Ministry of Agriculture, the other a special extra programme by the Scottish Office. This one that was referred to was asking the question, "If you do use different lectins and transfer them as a GMO into a plant, should we be developing new tests to try to assess other impacts that these lectins might have as an additional safeguard which could be put into the regulatory assessment process?" Dr Pusztai had been concerned to get this right and as a result of the *World in Action* team going to see him I had a discussion with him and believed that his concerns were legitimate. We therefore had an agreement that he could take part (because this is a publicly funded research programme done collaboratively). I also felt it was important to show that we were operating in the public as well as industrial and other interests, and that we were doing work on this topic. We agreed, however, that we should not release any unpublished data. In the event, as a result of the intensity of the interviewing, and despite all the attempts that we made to distinguish between unpublished data and published theories, unpublished data were presented in such a way as to give grounds for great concern in that they implied that there were very substantive adverse effects from genetic manipulation which we would have to assess. There was a bit of a muddle as to what experiments had been done so I immediately at that stage, having been led to understand that particular experiments were being discussed freely in the media, tried to put a stop to any release of unpublished data beyond the minimum. The plants used and these particular studies did not have anything to do with their putative release into the food chain. They were purely a theoretical construct where we are trying to look at how to go about testing the concepts, i.e. could we think of new ways of looking at this problem? So it was not a practical issue: it was a theoretical background piece of research. When it became clear that we were having to answer the question, with all the intense media interest in what exactly was done, I immediately invoked a system which I was familiar with in the Medical Research Council. In other words I suddenly had to say, "Hang on, there is confusion here. We must not allow confusion to occur in something of such enormous public interest. Therefore, please, Dr Pusztai, stand aside. I will

appoint people with great authority and independent of me or the Scottish Office or anybody else to assess all the data that seemed to have been talked about." I appointed Dr Chesson, because of his background in GMOs and so on, and three other individuals, two of whom were from outside the Institute. They conducted an independent report and we are happy to provide that to you today. In summary, after they had looked at the data made available to them, they concluded that for the present there were no grounds for concern on the basis of the studies that they had looked at. The immune studies, which made such an impact in the news, were very preliminary studies which were added as an extra to the original study which was an attempt to see whether there were anti-nutritional effects and impacts on digestibility and growth and so on. Therefore, from our point of view, we are happy to clarify the issues. There is no question of any malpractice. Of course, we did not expect that remotely with a man, Dr. Pusztai, of such prestige and known to be so scientifically rigorous. We confirmed that a series of experiments had been done and at present we believe that this background research should be published in a proper way—it should be evaluated by experts. That does not lead us at present—future research may—to the view that there is a need for major change in the way in which we assess GMOs. This is public research done in the public domain. We may in due course, as a result of new data, come to different conclusions, but I thought it important, particularly since we were coming today, to make these analyses available to your Committee and indeed to the world at large. We are doing that in two tranches: first, giving an overview but then reserving for expert people who wish to examine the data the details so that we do not prejudice, formally speaking, the proper publication and evaluation of the detailed experiments. I hope that that will be seen to be the proper way of conducting the process, my Lord Chairman.

Lord Moran

638. I understand that a formal audit of Dr Pusztai's findings has been carried out by an expert panel containing representatives from outwith the Rowett Institute and that a copy of their report has been sent to the Scottish Office. Is the report that you very kindly said that you would be giving to us that audit?

(Professor James) Correct, it is precisely so. I should say that this report—and Dr Chesson would be happy, I am sure, to talk about it—did of course properly go to the Scottish Office. It also went to the collaborating institutions who are not directly involved in the particular experiments that were being conducted on the nutritional and immunological reactions. What we are producing today has been seen by the Scottish Office and it has been seen and agreed by the collaborators. I have also now presented it to Dr Pusztai. I received on Friday evening some new data and new analyses from Dr Pusztai and they are going to the Scottish Office and to the members of the audit committee. His report has new data and further

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interpretations and that is part of the normal scientific process. So what we are releasing today is the audit report and a general overview that I hope the public can understand. We are then going to look in more detail at this new information that comes from Dr Pusztai and if there is a need to make a public state thereafter we will do so, but we would like to seal off the audit issue because the water got very muddled as to whether there was interference or misconstruction of the data. It is very clear that there were experiments undertaken and Dr Chesson can talk to that if you so wish.

639. In your Annual Report for 1997, in relation to one of your research items, it was said that "a significant finding is that plasma DNA can persist for appreciable periods in human saliva." Can you tell us what the results of the research which has now been completed are and what the implications of its findings are for eating genetically modified foods?

(*Professor James*) I could. I think Dr Chesson might answer it with greater specificity.

(*Dr Chesson*) We have a series of experiments on-going at the moment looking at the survival of DNA in the digestive tract because I think the assumption until fairly recently has been that DNA is very rapidly degraded and therefore poses no problems. In some preliminary work we did we found that isolated DNA from plant material would survive for periods of up to 20 minutes in the mouth, the implication being that this would allow time for uptake by the micro-organisms which exist within the mouth. The periods of survival are far less when the DNA moves further down the digestive tract to the point that when we enter the stomach we are talking about a few seconds. The interesting thing is that this work has not been taking place in isolation. There have been a number of studies which have shown that DNA does survive to a remarkable extent in the digestive tract and not only that, it is actually taken up by the host cells and you can detect it systemically in the body. We have to assume that DNA, which in some way enters the digestive tract either through food or micro-organisms, has always been taken up by the human body, but there is very little evidence that that DNA has been incorporated. We have had to re-think considerably our thoughts on the survival of DNA, and the assumption that it is automatically degraded and therefore not taken up by human tissue is palpably false, but there is no evidence to suggest that this is anything other than a perfectly natural event which has been occurring throughout human history.

640. You do not think it has any implications therefore?

(*Professor James*) There is no evidence that suggests otherwise at this point in time. On the other hand I do not think we can make blasé conclusions about the poor survival of DNA any more.

Baroness Young of Old Scone

641. Could I just ask another question about a piece of research that I think you were involved in and that is the MAFF commissioned work on the potential

for gene transfer between manipulated bacteria and resident micro-flora of the human gut. I understand this is now complete and I wondered what it was demonstrating and when we were going to see publication?

(*Dr Chesson*) That work is actually still on-going in a series of MAFF grants and there are a number of publications which have already come out from that looking at particular resistance genes and their survival. In the first part of that work the work was done in the context of the ruminant animal and the rumen and looked at their resistance to a very common antibiotic, tetracycline. Yes, we do have evidence of gene transfer between organisms.

642. And can you indicate overall the successive stages of these studies even though they are not yet published?

(*Dr Chesson*) Some of them have been published. Some of the work is still on-going.

(*Professor James*) Could I just come in and say that this is Dr Harry Flint's work and this is part of an on-going programme where it is becoming very clear that if one looks at the bacteria in the intestine, in fact there is far more plasticity than some might imagine. It is only by using new molecular techniques, which we have established within the Institute, that you are able to demonstrate the specificity of flow of particular components of DNA between different organisms. So what we first dealt with was the capacity of a plant piece of DNA to get into an organism. The other issue is whether you can become antibiotic resistant, for example, and will that resistance transfer. The evidence is that there is substantive transfer between different groups of organisms.

(*Dr Chesson*) The evidence is certainly that that transfer is possible and it almost certainly occurs on a regular basis. Having said that, you would then have to put that into context, of course, whether that transfer has any significance at all.

643. Are you prepared to say whether you find that of concern or not?

(*Dr Chesson*) I find it of limited concern where there is very extensive inherent resistance to a particular antibiotic. A number of the antibiotics that are used as selection markers in the production of genetically manipulated plants for instance make use of antibiotics to which there is very extensive resistance already in the organisms of the human gut, notably neomycin resistance where perhaps 20 or 30 per cent of the organisms carry that resistance. I believe that the transfer of resistance is a fairly common event. It is questionable whether the 1,000 or the 2,000 or the 3,000 events that may occur at any point of time in the gut has any significance against the millions and billions of organisms that are already resistant to that antibiotic.

(*Professor James*) Could I come in on that in terms of general questions because your concern is about the broader implications and Andy Chesson has brought up the question of antibiotic resistance. This is of great concern both in the UK and indeed in Europe. In the Scientific Steering Committee we established a new group to look at antibiotic resistance

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right across the animal kingdom and indeed the plant kingdom because in the Animal Nutrition Committee with which Andy Chesson is involved they are concerned with what should be in the animal feed. Then the question is what are the veterinarians doing with antibiotics and what are clinicians doing with them. That is why we are so concerned to get a grip on this problem. So there are many different dimensions to the story and the free flow of DNA between particular bacterial groups needs to be taken into that analysis. So we recognise that things are not rigid compartments. That is why it is important to look in an integrated way at the food chain.

Lord Jopling

644. Professor, two questions. First of all, I understand that Dr Pusztai was suspended. Could you say what his status is now with the Rowett and whether he has a future in the Rowett? The second point is that I have a note from Friends of the Earth who say that a certain amount of confusion has arisen because on one occasion you said directly to the media, and I do not have the reference of when, that the potato experiments did not use GM potatoes, whilst I understand a press release which was put out stated that experimental studies were on "GNA transgenic potatoes". I wonder if you could explain this confusion.

(*Professor James*) I apologise for that confusion. It was that confusion that we found so embarrassing because we were led to believe that in fact the studies that were of great importance, and that were being talked about in the media, much to my horror, before the television programme transmission, related to transgenic potatoes containing one of the lectins, Con A. What we discovered, and this is confirmed by the Audit Committee report, was that although the Con A transgenic potatoes had actually been produced (and we were just at the point where the nutritional evaluations have been done and the adjustments made ready for feeding studies) the feeding studies not been conducted with that particular lectin. We then, as a result of the audit, confirmed that a full set of experiments were just nearing completion on the snowdrop lectin GNA. So it is true, the transgenic potato studies were done with GNAs. It is also true that they were not done with the other lectin, the Con A, which was the subject of such intense media pressure on the first day. It was that first Con A problem that led to all the confusion and the statements that things were happening with transgenic Con A potatoes when in practice they could not have been happening because the Con A transgenic potatoes had not been fed. As to Dr Pusztai's status, I think it is terribly important that you understand that under the rules of the proper audit process we made no judgments as to what Dr Pusztai had or had not done. We then saw the transcript of the television programme where there was evidence that for a variety of reasons he had implied or stated things that were essentially unpublished. I regret that that emerged, contrary to what we had expected in the media. Dr Pusztai is a very distinguished 68-year old academic

within this Institute. He was suspended. He is no longer suspended because the audit is complete. He is engaged in a series of major European, industrial and Scottish Office studies, most of which are either coming to an end or going into a new phase of development. We have decided, because of the muddle, as I put it, that occurred with Dr Pusztai's work that these data and the set of studies be published in the normal proper way. This will involve Dr Pusztai in the normal way. When it came to the renewal of his contract at the end of December of this year—we have been doing that for eight years on an annual basis—we had to face the challenge that if we had to have an audit on this piece of work, how could we know that in another new study we will not suddenly have demanded of us, particularly if it is controversial work, a further audit? So I came to the conclusion that he should not be the prime investigator in future studies but that if different groups within the Institute sought to use him as a consultant then that was entirely proper. So Dr Pusztai has come out of this audit review exonerated and to be seen as we all knew him as an intense investigative scientist with an international reputation. There was a muddle in what was being said in that first 24 hours which I regret. We have now clarified the issue and the detail of what in fact will emerge from all these studies will be put through the proper process of evaluation by peer review and I will be discussing with Dr Pusztai his latest data. There is no way in which as a Director I will suppress, manipulate or manoeuvre anything in relation to these studies. It is important that what is produced experimentally is published and put into the public domain.

Chairman: Thank you very much, Professor James. We will read the audit with interest. I think we ought to try and press on now.

Lord Gallacher

645. Professor James, in this inquiry we have encountered many more risks in relation to the environment than to human health. What is your opinion on the safety and risk of genetically modified foods?

(*Professor James*) My Lord, that is a very general question. I am very familiar on a European basis with the increasing concern about the general environmental issues. What we have been concerned with predominantly in our Institute is the animal and human impact. I think there is much more emphasis on the environmental, but I think it might be helpful if Dr Chesson gave you an indication of the categories of safety that have to be considered with GM foods because I think it is very difficult to get a generic yes or no response to that particular question.

(*Dr Chesson*) I think I would agree with that. I think there is a tendency to use GM plants, GM foods as a catchall phrase. It is very evident that when you actually look at each of these individual genetically modified plants you really have to consider them on an individual basis from the viewpoint of safety aspects because each is quite different, each contains different populations of introduced genes, each has different

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characteristics, each has different potential uses and potential dangers for the environment and for human and animal health. I think looking at the 11 or so genetically modified crops which my working group has actually agreed are safe for release in Europe, then I think probably the greatest debate was about the potential effects on the environment and the horizontal transfer of genes, particularly herbicide resistants into other crops and particularly those involving oil seed rape. I think this is going to change in the future. If you look at the sorts of products which are currently undergoing trials and the sorts of products which are being considered at a laboratory level, I think we are going to see some quite novel constructs which are going to ask and raise a whole series of quite novel questions and certainly questions which have not been raised to date. So I think it is very difficult on a generic basis to comment on the safety of GM foods. I think you can only really do so on a case by case basis. Perhaps you would allow me one minute just to exemplify this. One of the crops which has recently been considered for release is the genetically modified tomato, the products of which have been in the market in the UK for the last two or three years. This genetically modified tomato is genetically modified by introducing exactly the same gene that the tomato already produces, it is almost identical. It seems to me that the risks posed by that as a piece of genetic engineering are relatively small compared to the risks introduced by, say, one of the lectin genes that have been considered previously, which opens up a lot of other questions. Curiously enough, there is one lectin gene which is already used in European agriculture and that is the Btk toxin, the toxin which is used to confer insect resistance, but the Btk toxin is unique. It is the only isolated toxin we have used for 35 years as an insecticide. It has already been added to plants which have entered the human food chain. So unlike other lectins, we have a considerable amount of historical support for the suggestion that that gene product is inherently safe within the human food chain. You cannot say the same about novel lectins for which we do not have the same body of historical evidence. So I think the whole point of risk assessment is that it does have to be on a case by case basis and you really cannot make any generic conclusions about the safety of GM crops as a whole.

Lord Rathcavan

646. What is your view of the current EC assessment process for novel foods and its implementation in the UK?

(*Professor James*) I was involved originally in the Scientific Committee for Food and the sub-committee that was involved in developing the proposals for novel foods regulations. I am not now on the Novel Food Committee in the UK, nor indeed now on the E.U. Scientific Committee for Food so I may be slightly out of touch with the precise state of affairs, but there is quite a complex process involved. I think that there has been an attempt to speed the process by which novel foods can be assessed such that there are time limits put on, first of all, a national assessment

that then goes into Europe for distribution to other national groups who have to make a response. This is quite a complex process. I believe—I could easily be wrong—that that has not yet been tested properly. Certainly I am Chairman of the nutritional group of COMA, i.e. the Committee on Medical Aspects of Food Policy, and we have had to generate an extensive list of consultant colleagues so that we can turn round a view, should we be asked for it, very rapidly. In the old days we came together and looked at it very carefully. Now we have to respond after 60 or 90 days—I always forget what the time limit is in this process. That is a scheme which may have to change, but I think it will have to change on the basis of experience. At the moment there is an attempt being made to have an open process that allows every country to make a response and allows every expert group to look at it, but the speed is such that many national committees are worried as to how they are going to cope. I think it is fair to say that.

647. Do you think the assessment of genes which do not have proven track records for food use is adequate at the moment? Is further research needed in any area, for example in allergenicity?

(*Professor James*) Dr Chesson and I were discussing that a couple of days ago and he may wish to comment on this. I think that is a very difficult topic to assess, how do you know what level of "allergenicity" we normally have with a range of foods? There is a big dispute about that. If one is going to introduce a particular protein genetically one can look at the structure of the protein and ask if we know that this type of structure causes allergies. But if you say the structure may be slightly modified in this particular plant, how on earth are we going to assess whether that is going to induce in a very small subsection of the population an unknown allergenic response? I am not sure how we are going to cope with that yet. Perhaps I can just call on Andy Chesson to put me right if I have misled the Committee on that.

(*Dr Chesson*) I think I agree, allergenicity is a particular example of some of the issues that are facing regulatory bodies. As Professor James said, the standard technique at the moment is to compare the structure of the unknown protein with that of known allergens. There is an assumption which may not be warranted, which is that if there is no strong similarity then it is probable that that protein is not allergenic. That is not always done in isolation because there are also toxicity studies that are made on all of these plant materials when one might expect these sorts of problems to be visible.

Baroness Young of Old Scone

648. This is a subject I suspect near to your heart, Professor James, the whole business of trust in food safety and measures needed to try and improve that trust. Do you think the Food Standards Agency is going to do that in the area of GM foods?

(*Professor James*) When I proposed the formation of the Food Standards Agency and its structure, which seem to be accepted by the Government, it seemed to

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me that this business of trust is one of the most difficult ones to achieve. It was because of the complete lack of trust in the current process at the time that I proposed that there should be a very new process in British assessment procedures. We needed to open the debate not only to the technical experts but also to have consumer representatives involved and have everything done in a very open way. That seems to have been accepted essentially by pretty well everybody. Last week I was in Paris discussing with the French, the Dutch, the Danes and United States groups exactly this issue and we all came to the same conclusion. If you are going to establish trust in the public mind it is quite difficult because everybody will complain that the media gets it wrong, but I think you have to have a mechanism in play where you need consumer representatives, however they are chosen, actually challenging and being involved in a major way. These individuals, who themselves have the trust of consumer organisations, come to recognise or challenge and change the assessment processes so that you begin to build confidence that nobody is playing games with the process of assessment. That is what I believe should be developed in the United Kingdom. If it does not come I think we are going to run into trouble. I think we have to get away from our, may I say, traditional British view that I am the expert and you do not know anything about the problem so why do you not listen to what I say? Furthermore why should you bother to question me because I am sure I am right. That is a crazy way of doing it. On the Novel Foods Committee, we had consumer representatives and Professor Burke, who was the Chairman, and I had, as well as others, come to the view that the consumer representative was enormously valuable because she made us realise that our judgments were being put in a context which just would not be understood by somebody who had a legitimate concern. So we changed our assessment process and the way in which we reported it. After the Food Standards Agency report which I produced at the time of the election I was then asked by President Santer's office in Europe to go and talk to them about the same problem. We are currently in the Scientific Steering Committee, the Chairman and myself and two others, trying to put together a new view of how we should begin to build European trust in a new way and considering specifically the GMOs as well as other risks. At the moment there is a European Parliament in one corner, the Commission in another and then there are national governments in another corner with Ministers. There is a disjunction and a failure to interact with the public. I think we need a new mechanism on a European basis and that is something that we agreed on Friday last in the Scientific Steering Committee that we would begin to look at. I do not have the answers. I think we have got to explore this. I am quite sure we are going to have to keep changing the system until the public, the European Parliament and this Parliament are convinced that we are beginning to engage the public, the industry, the scientists and the technocrats in an appropriate way. I do not think we have got it right at the moment.

649. Is there anywhere that has got it right that we could learn from? There does not seem to be quite the same degree of distrust in the United States. Is that by chance or is the process better there?

(*Professor James*) In the United States, following our report, they have been re-evaluating what they are doing. There are now proposals for the USDA dealing with the agricultural animal side of food safety, to come closer to the FDA. They have a much more open public assessment system in the United States. There is a much greater freedom of information. There are objections to committees meeting in public, I understand, but they have very public discussions. When you talk, as we did last week, with the US experts, they just assume that experts have to justify their every opinion to anybody who comes along. I do not think that we have that determination in our culture and I think that that in part is why in the United States you have less of a frenzy, compared with our going into a great spiral on one of these GMO issues.

650. What are your thoughts on the potential delay in setting up the Food Standards Agency?

(*Professor James*) I recognised before the Election, talking to the Independent Constitution Unit, that the potentially incoming Labour government had a huge legislative load and so my original proposals pre-supposed that the Food Standards Agency would be going through in the next session of Parliament. I therefore proposed, because I knew the question of trust was important, an intermediate solution where you had, if you like, a shadow commission for this agency. That was deemed to be "unconstitutional" in that it presupposed, despite my having checked it with the Constitution Unit and with Cabinet Office officials, that Parliament would agree that a Food Standards Agency should be appointed. If a Food Standards Bill does not go through this next session of Parliament then there is a real danger, with all the heat, debate and concern about GMOs, about BSE and about at least a dozen big issues—that we are going to delay the building of trust in our food system. So I think that some mechanism may need to be devised whereby the public interest is brought in now and in a more overt way. How that should be done I think is a matter for debate.

Chairman

651. Is that something along the lines of the Stakeholders' Forum which the Government announced they were considering last week? Would that fit the bill from your point of view?

(*Professor James*) Yes. I do not know the details of that, but I think we need a process which effectively begins to allow the challenge and debates to be operating in a much more public way. That is not going to solve the problem because quite clearly everything that I have learned since I produced my report amplifies the need to have a coherent integrated approach to the assessment and safety checking process. I think that throughout the world other governments and other organisations are coming to the same conclusion. So I do not think it is a novel idea at

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all. I think it is now considered to be routine and the question is how to do it properly.

Lord Jopling

652. On that very point, Professor James, Ministers came to this Committee last week. After having read the transcript of what Mr Rooker said on the matter of the FSA, it is clear that they are not going to have a Bill for primary legislation in the coming session because it is very clear that they are going to produce a draft Bill and spend the next year doing a form of consultation, which is the new Parliamentary process which the Procedure Committee in the other House have devised, and therefore we shall not get the legislation until the session beginning a year from now and it will take probably most of the year to go through, which means it will not be on the Statute Book for another two years, so that means three and a half years from the Election. Would you just point out some of the dangers you think there are in addition to what you have said already as a result of this very long delay?

(*Professor James*) In my original report I believed that it would take between three and five years from the establishment of the Food Standards Agency to get to the point where one would build trust and begin to see the impact of new developments associated with that Agency.

653. If I might interrupt you, if you say it is three to five years after it is set up, that is 6.5 to 8.5 years from the first suggestion.

(*Professor James*) That would be my concern, my Lord. The issue is what could currently be done to begin to anticipate the Agency and how is one going to begin to engage the public and all the stakeholders. I believe there is cross-party agreement on the general structure of this Food Standards Agency. I think that we now need to legitimately address how some of these issues could be developed and I would have thought a provisional Commission would be a sensible approach. I stand corrected if this is unconstitutional.

Chairman: We now come to questions to do with the EC advisory committees.

Lord Jopling

654. Professor, the proposed revision of Directive 90/220 will introduce the consultation of the European Community's scientific advisory committees when there is a dispute between Member States. This Committee is going to Brussels next week to talk about this whole area and I think we shall go with a feeling that there is a certain muddle in the way that these committees are appointed. I would like you to tell us how you see the structure of the committees, how you see the membership of the committees. Are they balanced with regard to scientific expertise or between representations of Member States? What do you think needs to be done to improve what to some of us seems a real muddle, to use the word you used earlier on in the hearing, over this situation?

(*Professor James*) I think that I should respond by saying that I found myself suddenly appointed to the

Scientific Steering Committee as one of eight independents from Europe and therefore was promptly involved in the appointment process. It was interesting that the Commission asked us to go at break neck speed. We find that the Commission want to involve us usually at one to two or three weeks notice, whereas, like you, we are booked normally a year ahead with commitments. In those appointment groups I discovered that in fact the Commission had put out a call for other groups to propose particular individuals to be considered for an expert committee. I found myself in an expert committee where I personally had no expertise but where I was operating as the Chairman. The process was one where different Commission officials with experience across the range, including, for example, DG V from Luxembourg on public health, DG III on industry, DG VI on agriculture and so on, all had representatives and we looked at the portfolio of scientists. There might have been 150 portfolios to look at in this one area. My particular area was cosmetics. We looked at these portfolios and we were asked to produce the best experts without having regard to nationality, on the basis of their experience, range of involvement, scientific expertise and so on. We were asked to produce, if I remember correctly, about 30 experts and they would choose 15 to 25. It was made clear that they would choose 15 to 25 from our group taking account of geographical distribution. After we had chosen our 30 we then met in quorum because each of the eight of us on the Scientific Steering Committee had actually chosen with officials 30 or so experts for each committee. We then discovered there was an overlap of experts on different committees. We had to resolve their problems and we were then told that the Commission would have to make the final decision taking account of geographical expertise. I think it is not breaking confidences if I say that one of the messages that came through powerfully to every one of us—I was the only UK person amongst these eight—was that they always had a huge number of British experts who came up at the top of the pecking order on the basis of international analysis. The plea was made that if possible we should not have more than five UK people out of the top ten because if they produced a scientific committee that was stuffed with the British in every particular committee it would be seen by the European Parliament and the public as unbalanced. Therefore, we chose, taking account of expertise, about four or five British to put in our top 20 and therefore there was an element of geographical pressure, but we had started off on the basis just of scientific expertise. Does that help?

655. I wonder if you could answer the last part of my question which was how you feel the whole system could be improved and particularly the interlocking of the various committees. I think there is also an argument that there is a muddle there too.

(*Professor James*) Thank you. I should have addressed that. That is one of our principal concerns on the Scientific Steering Committee. Several of us are involved each time in wondering about the interplay. You have just heard about Dr Chesson's secondment

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from the Animal Nutrition Committee to the GMO Working Party. That was what we perceived to be important. When GMOs came up it was the steering committee that looked at this and said, "You cannot just deal with this in narrow constructs, we are dealing with a broader set of issues." Therefore, we finally agreed to have a working group working predominantly with the plant committee on plant GMOs because that is where most of the work was coming through, but we then inserted membership from other committees. We are still not convinced on the Scientific Steering Committee that we have got it right. We are not criticising the GMO Committee, but there are very broad issues of enormous public concern and one of the big issues for the Scientific Steering Committee is to try to tackle precisely your concern, i.e. how are we going to ensure that we do not have a narrow focused yes or no answer to a very specific question from the Commission about a GMO and whether or not we agree that this or this construct is or is not safe on the grounds of X only. How do we get the proposed genetic manipulation into proper perspective? It is this sort of issue that we are concerned with and we are on the point of trying to think through the problem. You must also know that there is a discussion about the re-organisation of the European Commission as a whole and the question is, on the basis of our year or so's experience, can we do things better. I would not like to give an instant answer but I think you have to understand that we have been in an amazingly rapidly evolving process where, when I walked in last September, a year ago, there were practically no staff in DG XXIV. It was incredible. I wrote all the papers on BSE for those committees, and Dr Chesson operates similarly. We will come later to the question of the time involved, but the substructure, the organisation, is only now being put into place, so you can run rings around them in terms of the proper process and how it should be done. I think they are improving. DG XXIV are very conscious that they have to get it right and they distance us from a lot of pressure that comes in from other directorates general, but I would not for a minute say that the process compares with, dare I say, the efficiency with which the secretariat administrators and scientific people within the British Government service their committees here. The contrast is really quite startling, not because you do not have very talented people in Brussels but they are absolutely frantic trying to cope with a highly complex interplay of nations and special interests.

Lord Moran

656. I wanted to follow up Lord Jopling's question by asking about the operation. You have already said something about this and I wondered if you could tell us more about how, in fact, committees operate, whether you think they are well organised, whether they meet frequently and, in your view, frequently enough, and how much of your time they take up? You have told us you have to write the reports. It sounds as though it is a very considerable commitment?

(Professor James) I would be happy to answer that. Perhaps I should let Dr Chesson come in first, because I never see him at the Institute any more and I believe that he spends all his time in Brussels which he denies!

(Dr Chesson) I will make a specific answer to your question but I would like to emphasise one thing that Professor James said before I answer your question, and that is to make the point that these committees are very much in a process of transition. Up to a year ago, or just over a year ago, all of them operated out of completely different DGs and to a completely different remit. One of their major concerns was actually assessing efficacy of products, for instance, which is no longer a concern of these committees. So the way in which the committees operate has undergone a radical change and is changing even now as we talk. We are evolving the way in which we operate. The relationship to the other DGs is quite important because a lot of the DGs are still trying to operate on a historical basis, are trying to demand answers to questions which are no longer really the remit of the committees, the scientific committees operating out of DG XXIV. The primary remit of the committees operating out of DG XXIV is in terms of safety assessment, risk assessment. The time commitment is actually quite demanding. It depends very much on the nature of the scientific committees. Some have a very heavy workload, an extremely heavy workload. The Scientific Committee for Animal Nutrition is probably one of the heaviest. It will meet in plenary session virtually monthly, at least ten to eleven times a year for a two-day session, but, like any organisation, the majority of its work is actually done in small working groups. Those working groups may have a lifespan of a few months dealing with a fairly tightly defined question or they may have a lifespan which is likely to be considerably longer than my own. In the case of genetically modified plants, for instance, one cannot see that working group ending its activities for many years to come because these questions are not going to go away. So there would be at least as much time spent in Brussels in working groups, so I think you are talking of something in the region of four days minimum a month for anyone concerned with one of the more active scientific committees and that, of course, excludes the work that needs to be done in preparation for those committees.

(Professor James) And that is enormous. When Dr Chesson took over his work on animal nutrition, a previous expert from the United Kingdom actually used a lorry to transfer the Committee documents to his office. I personally, on the Scientific Steering Committee, have been heavily involved in BSE and was responsible for producing the BSE analysis of how we should look at BSE on a European. Therefore, I am now on a BSE ad-hoc group and on two of their sub-groups and two other sub-groups of the Scientific Steering Committee. I reckon that we are very unusual in Britain in that the British are seen as totally independent experts and it is seen that we produce our own reports miraculously out of thin air. On Friday we discovered that several British experts have resigned

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from sub-committees because they cannot cope with the demands of the workload. Colleagues on my same Scientific Steering Committee have ten people supporting them, paid by national governments, to integrate and sift and generate the background information. I am trying to find a means of supporting Dr Chesson more effectively. I am very fortunate in that I have at the moment one person, for whom I am trying to get funds, to help me. Without her I could not have helped with the Bone Report that was passed last Friday on BSE or the Sheep BSE Report which I helped to develop last month and so on. The original BSE report to deal with the US/European trade war threat I produced over two weekends, curiously enough with my wife working flat out with me to get it through by three o'clock in the morning on the Monday morning deadline. That is the "ad-hocry" that is being demanded of us. I have done an analysis of the amount of support in Europe compared with the United Kingdom and have checked with several other governments, and I calculate that the committees in Europe are supported by between a tenth and a quarter of the staff that we have in any major national government committees in Europe. If you have an expert committee here you may have one or two experts and administrators and secretaries. But the poor officials in Brussels operate as a single expert across three committees as well as ad-hoc sub-committees, and only now is he acquiring a secretary. It is a nightmare problem. The Brussels staff are working 12-15 hours a day and they work remarkably well. But the structure of organisation for the long term future of Europe is in my judgment inappropriate: I am in the process of telling the

European Parliament just that. 657. I was just wondering, fundamentally what do you think needs to be done to make it more sensible and effective?

(*Professor James*) There needs to be a very substantial increase in the secretariat with scientific competence enhanced with administrative back-up. I think it should not be required that we produce chapter and verse on every document that is produced, often with demands that we produce it for public release with, quite often, every decision involving hundreds of millions of dollars in trade. We are expected to produce that at a day's notice and approve it in a session with ten other items on the agenda. That can only be done if you have got UK experts with proper back-up here in the United Kingdom. It needs to be specifically recognised that these experts do play a role for Britain by acting independently in the European context so that the European system is developed in a coherent way and so that we begin to get a proper interaction and national interflow of discussion. The alternative is to go back to a subsidiarity process where the United Kingdom does everything. The danger of that, particularly as Europe expands, is that you presuppose that another country can do things as effectively as the United Kingdom and my judgment is that it would be unwise to go down the subsidiarity route because there will be a political necessity to spread the load around the countries. I think we would be better off to have as effective representation in

Europe by British experts as we can with an effective European system and the capacity to monitor from a United Kingdom base what Europe does.

Lord Gisborough

658. How do you rate the quality of the advice that these committees give? Does the Commission tend to accept your advice? Is consulting these committees the best way of resolving inter-Member State disputes?

(*Professor James*) I am biased in response to your first point. If we have actually chosen supposedly the best experts in Europe to go on to those committees then you would expect that the advice is good. The advice is pretty good. Dr Chesson thinks so too. I believe that the pressure of the last year has been too intense to get really very well balanced, beautiful judgments that are explicit and clear in all aspects. I think that is where secretariats and so on could help. I have forgotten the second question.

659. Does the Commission accept your advice?

(*Professor James*) The Commission accepts our advice in the sense that you can see DG XXIV takes our advice as independent and certainly our steering committee, and I think the GMO committee have very substantial impact. But do not forget that there is a Standing Committee of governmental officials who essentially are negotiating with the Commission on the basis of our advice. It is quite a complex process. We are independent. We quite often have no knowledge of what goes on in those Standing Committees. We are suddenly asked questions by the Commission and we have to have it explained to us why we are getting that question. Quite often the question has emerged from a battle between one national delegate and another not in our view on a scientific basis at all but as part of, dare I say, political manoeuvre and trade-offs of different views. To answer your third point, the Commission then promptly comes back to us because they want to be seen, if at all possible, to be independently operating for the benefit of Europe. They, curiously enough now, are seeing DG XXIV as having the independent group that at long last, thank goodness, is giving the Commission advice as they struggle to try to make sense of the battles in the standing committees. I hope that is clear.

660. Is it more important to improve the quality of the committees' advice or the method of their operation?

(*Professor James*) I think it is more important to improve the method of their operation by having much more effective support and by having much clearer specification of what the processes are within the Commission. Then we just do not come into a problem blind but know that a particular DG has had a meeting with a Standing Committee, that this issue arose because there was a dispute between x and y on such and such and that is why the question has been put to us. Then we could begin to understand how to address that issue instead of just having "what do you think about this" and a very preliminary limited explanation. I think there is a lot that the Commission can do and I think it is in the process of recognising that. I am not

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[Lord Gisborough *Contd*]

in the business of attacking the Commission today, they are desperately struggling to cope in my view.

Lord Gallacher

661. Professor James, we turn to the question of stopping the clock. Under the proposed revision of Directive 90/220 it is proposed to stop the clock while the scientific committees are consulted to resolve inter-Member State disputes, even though if the clock was not stopped the committees would still have three months in which to formulate and deliver their advice. In that context are you in favour of stopping the clock?

(*Professor James*) I am in favour of stopping the clock but Dr Chesson is under the gun on GMOs. Perhaps Dr Chesson will respond and disagree if he wishes.

(*Dr Chesson*) I think in practice the clock is automatically stopped. You are quite right that often there is a three month period but you have to remember that most of this is being done on a voluntary basis. If this was a full-time committee or if you had experts who were seconded permanently to these committees then I think the three month period might be a reasonable time span, particularly given the time available to people who actually have to evaluate very complex dossiers. Sometimes people do not understand quite how large they are. I once had delivered 84 volumes of a dossier on virginiamycin resistance. This is not something you would take home and read overnight. The expectations and the amount of information you have actually to consider requires time. If the evaluation is going to be sound and thorough then it seems to me that one should not force a time period for a reply.

662. Can I ask just as a matter of information, is all this having to be done in all of the languages of the Community?

(*Dr Chesson*) The tendency is for the working language to be English, as you might expect, certainly in the working groups. In the plenary sessions there is simultaneous translation. The dossiers are provided usually only in one language and that is not necessarily English.

(*Professor James*) Could I add that stopping the clock is a very sensitive issue. It is exasperating for some groups and industry, for example, to put forward a proposal and find that wherever they go at each step the clock has been stopped. I think we need to look at that in terms of the mechanism by which the approval process is gone through. If Andy Chesson has 84 volumes to consider on one particular topic then you can hardly expect an international group to come to a conclusion on that within three months. However, the issue is how many steps has it gone through before this key set of decisions is taken. I think that is where the improvement should be rather than in specifying that he not only has to give up his Sundays, he has to give up his days at the institute routinely as soon as somebody somewhere demands that he reads another 84 volumes.

Chairman

663. So you are in favour of stopping the clock?

(*Professor James*) Yes, I am in favour of it but I think we could get a more efficient method of analysis which in effect speeds the general process up but does it properly. I think we need both and that is the challenge.

(*Dr Chesson*) If I could just make one comment. I think in relation to genetically modified crops we are going to run into a problem where the time spent on evaluating these materials is actually going to increase and not decrease. That relates to the way in which the legislation is going to be handled. At present scientific committees are asked to consider the crops under 90/220 primarily for release. If the material has a food application then it will also be considered by the Scientific Committee for Food, under EC No. 258/97, and we are about to have introduced a novel feeds regulation to match the novel foods regulations, so if it has a feed implication it is liable to be examined under the novel feeds legislation. So it is going to be very crucial as to how those various pieces of legislation are organised and how the scientific committees are organised to deal with them. My personal view is that it ought to be a one-stop process, that a composite committee ought to be able to respond under all three pieces of legislation. What concerns me is information passing from one group to another group asking almost exactly the same questions and requiring almost the same evaluation in each case. I think that is a foolish waste of time. The other thing that concerns me about that process is that there is a tendency for things to slip between the cracks between the various evaluations. You may have a case where you have a genetically modified plant which one committee has a slight concern about but not necessarily enough to suggest that it should not be released for growth in Europe and a second committee may have a slightly different qualm about the same material but the two never get together and therefore there is never any overall weight of evidence which would mitigate or question the safety of this material. There is a great deal of danger in splitting up what is essentially a single problem, a single evaluation, and being seen to be handled by a number of different committees and processes.

(*Professor James*) That is exactly what we are going to consider. Having realised this in talking with Andy Chesson I wrote to the chairman of the Scientific Steering Committee and he circulated my letter dealing particularly on GMOs. It is these sorts of issues that we think we should be tackling as a coherent whole. We are proposing that we need to rethink this in terms of the way the Community handles the problem.

Lord Redesdale

664. There are obvious implications for the developing world through the use of GMOs but could you say what the implications are for developing countries considering international property rights and also the use of patents which might actually affect them adversely?

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[Continued]

[Lord Redesdale *Contd*]

(*Professor James*) As some of you know I am Chairman of a United Nations' Commission at present looking at future food needs on a world basis. I was privileged to be asked to do this by Richard Jolly who is the leader of the UN Development Report. Dr Gro Brundtland and Mabul ul Haq and I were appointed as the three commissioners. Dr Gro Brundtland now is in charge of the World Health Organisation and had to decline and Mabul ul Haq, former Treasurer of Pakistan and founder of the UN Development Reports, unfortunately passed away suddenly earlier this year as you will know. We have been looking at your problem and we meet again in Madras in three weeks' time to look at these very issues. There have been two recent major meetings in Britain. You may be familiar with the Royal Society meeting on this issue and the Rank Prize Fund meeting which has just been published in New York on feeding a world population of more than eight billion people. If you also look at the work of the new director of the Rockefeller and the way in which the Rockefeller Foundation is going about tackling this problem then it is clear that they are very conscious that there is a huge issue of the Third World. If you look at global food needs we have a problem of whether we can keep putting up the plant yields, because that is fundamental to being able to feed the world. The way in which one puts up the yield is by manoeuvring, choosing, selecting crops that can handle a limited water supply, salinity, and so on and so forth far more effectively. The amount of land that is going out of production is at the moment worrying because of the huge growth of the mega-cities. The Third World has an enormous need for help. What you are pointing out is exceptionally important and was highlighted by UNESCO two or three weeks ago: there is a huge intellectual or, if you like, capital asset gap between the First World and the Third World. If you look at the new analyses, and I have recently been to Washington to the International Food Policy Research Institute, they have come to the conclusion that the Third World has a desperate need for enhanced agricultural research. In Europe we have tended to conclude that agricultural research post-war now needs to stop or be reduced substantially because we have got too much food being produced. On a Third World basis, however, agricultural research is desperately needed because to get the increased crop yield you need the best new developments—of selection with this selection to include GMOs. The question is how are you going to get that through on a practical basis. I think that we tend to go for magic bullets too often when we look at Third World issues. New analyses suggest that if we are going to make progress we have got to have the same major community involvement that has been shown, for example, in Tanzania, in Thailand, in parts of India, the Tamil Nadu project and so on. I think that M S Swaminathan, the ex-director of the Rice Research Institute, is convinced that we have to have a panoply of different crops, not just a few GMO crops. I think that if Britain is interested in helping the Commonwealth and the Third World it should be seriously thinking about how best to develop schemes with Third World countries so the marvellous capital assets in intellectual terms of British science

and of British companies can be linked in a way where the Third World does not believe that they are being raped—I choose the word advisedly—by companies and other Governments who make use of precious assets from, for example, the Amazon Jungle in terms of crop varieties. How are we going to cope with that? I think it is a huge challenge that has not been addressed properly as yet.

665. Going on looking at patent law over these issues there are countries which in the present system in reality on the ground will not be able to afford certain crops. Peasant farmers will not be able to afford these enhanced crops. How is that gap going to be bridged?

(*Professor James*) I think it is a major issue and I do not have an instant answer. The research community, particularly in the United States, for example in the Rockefeller Foundation and elsewhere, are very much involved in charitable funded work for the Third World where they are trying to protect patents. I think there is a potential for a new dimension of private-public partnership where in fact national governments with World Bank/IMF support became involved. The IMF and the World Bank, I am sorry to say, in the current crisis have shown a complete failure to look at the social, economic, agriculture and human dimensions of structural adjustment. They are not recognising that actually a much more sophisticated response is needed. I would be in support of the World Bank and the IMF being much more locked in with the major companies in trying to develop new ways by which the Third World can profit where the industrial countries know that they are not going to get the same return but they have not put in all that money themselves either. So it is a joint venture for Third World benefit.

666. Can I just ask one more question. There was some talk that the Australian Seed Bank were thinking of actually patenting seeds within what is seen as almost a global resource, they are actually patenting seed stock. Do you think that is tenable?

(*Dr Chesson*) Personally, no. I am very concerned about the whole restrictive process of patenting of genetic information, cotton being a classic example. I think there are a number of issues that come out of this technology. There are serious dangers for the Third World. One I can see is actually the increasing emphasis on cash crops for Third World countries. This has already proved to be a major problem for many African countries where you get international companies producing cash crops of little value to the actual country itself but pushing the food production for that country out into the marginal lands. As we see more and more GM crops with higher value products it is going to be increasingly attractive to grow crops like this where there are low labour costs. I think that is going to put even more pressure on the existing lands within the Third World. There are dangers concerned with the introduction of GM crops in the Third World. There are clearly very good potential benefits but I am not sure that these are always given the highest priority by breeding companies which are based essentially in the US, in Europe, in Canada and

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[Lord Redesdale *Contd*]

in the developed world. For instance, you would probably have more impact on nutrition in the Indian Sub-Continent by increasing the degradability of the rice straw fed to buffalo and other animals than actually increasing the seed content of that rice because this would have a major impact. I think you would be hard put to suggest to breeding companies that they could get an economic return on doing that sort of research. I echo very much what Professor James was saying. I think the only way forward is for Government to encourage a partnership in which scientists from the Third World are not actually brought over to countries and put to work in research institutions for the benefit of the research institutes, but are possibly organised such that they can do research within multinational companies on projects which those multinational companies might not have given a high priority. I am sure there is a mechanism under those circumstances for working out IPR to the benefit of both. There are ways forward if one is reasonably imaginative.

Lord Grantchester

667. It is unclear from the Directive whether the scientific advisory committees, when called in to resolve inter-Member State disputes, will comment solely on the dispute or whether it will re-examine the entire dossier. Bearing in mind what you said earlier would the latter concern you and is that the more likely outcome at the moment?

(*Professor James*) I think that in coping with a particular question quite often there seems to be a very narrow area of dispute. In practice when you look at it some of the issues are really quite broad. It seems to me that most of the scientific disputes in Europe will already have gone through a scientific committee which will have looked at the entire dossier of data. I do not think it is as bad as you may think. If some quirk comes up and you think a terrible committee is going to take another three years before it comes up with a view on it, then I do not think that is going to happen. I think that we can get into trouble, as we discovered on Friday on bones and BSE, if we take a very narrow perception of what is being disputed within the standing committees. I think one has to take a breadth of perspective without necessarily going back and re-examining the whole dossier. I am sorry, that is not a straight answer.

Chairman

668. So you do not think that the scientific advisory committees are being abused? You do not think they are being asked to put aside the wrong questions? They are overloaded but they are not being misused.

(*Professor James*) On the whole I do not think they are being misused because I think DG XXIV is really very intent on developing a new culture which is very different from the old culture. They are, in a sense, protecting us from the old schools. How that is going to work through I do not know. I do not think that they are abusing us. Certainly in my experience

we get quirky questions from other Directors General which have very complex political reasoning behind them and usually we discover what that is and then we come back and give the general picture without regard to the political machinations.

Lord Rathcavan

669. Can I ask you a question about the precautionary principle. Do you agree that the step by step approach of the precautionary principle is the way to proceed with genetic modification? Is it being implemented in the United Kingdom in the right way in handling GMO release applications?

(*Professor James*) I think Dr Chesson is better answering that but I would make a general point about the precautionary principle. This has come to me powerfully in the last 12 months in terms of BSE. If you take the precautionary principle to its extreme you will say "I think there is a theory that there is a problem in this particular area, therefore if there could be a problem we will not actually allow anything to proceed until in fact we have got a beautiful scientific analysis of whether that theory might be operating or not". In practice I think that if one takes that to the extremes that I have seen some scientists taking with BSE, one would get to the point at which you would shut down the whole of the agricultural food supply in Europe, and I mean that literally. In terms of GMOs I do not have enough practical experience of that step by step approach to know whether that is a big problem in Dr Chesson's committee.

(*Dr Chesson*) I have a horrible feeling that it is actually an excuse for inaction. Bear in mind what has happened with antibiotic resistance markers that are used in the selection process with GM plants. There has been an enormous debate over the last few years about the use of such markers. The interesting thing is that the companies have responded to this debate because they still have a market to sell their crops, they are still very anxious to get these crops into Europe and growing in the US. They have responded by actually improving their technology to the point where the products that are coming on line now simply do not have antibiotic resistance markers. I am not convinced that if there had been a precautionary principle in action there would have been the same incentive, if you like, for the companies to make those changes. I suspect that it can work in both directions. If you have the precautionary principle it also seems you know precisely the question that will need answering before you allow the next stage to proceed. Again, I am not sure how you actually arrive at that question.

(*Professor James*) I was involved in the novel foods where we were pretty angry there were antibiotic resistance markers coming through into the food chain. We explicitly stated so in our public releases and so on. I think that the precautionary principle is, if you like, a very good way of starting because you are thinking about all sorts of issues. The question is do you stop everything on the basis of theory. I think that is back to the discussion about trust. You have to get to the point where you have people with genuine

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[Lord Rathcavan *Contd*]

concerns so involved in the process that they realise that it is reasonable to go forward not knowing everything at this stage. If there is real concern you put in mechanisms whereby you can survey the potential impact of the changes so you can have an early warning should there be a problem. If you do not believe that balancing the judgment is really the issue, then you need to give me examples of how there might be some obscure problem which emerges when a balanced judgment is made. We are always going to have that problem when we are trying to make judgments. I think to balance the argument we need a lot of different groups involved in the committees, so you can build reassurance. For example—people who are very much involved in Friends of the Earth ought to be brought into this discussion and not rubbished; neither should the industrial companies be rubbished. We have got to build a new mechanism for getting a proper interchange so we understand the dimensions of these issues.

670. You expressed your concern about the use of antibiotic resistance marker genes, and we have had many discussions about that in this Committee, should they be banned and are there other genes to use? Would you have the same concerns about the use of fish genes in plants? We have heard about a gene from the arctic chard being used in some plants as a sort of anti-freeze.

(*Dr Chesson*) As I said, you have to look at everything on a case by case basis. You have quoted two examples which are quite radically different. Yes, I would have questions to ask in both cases. Those questions would be specific to the genes that are being introduced. If one can answer satisfactorily those questions then my concerns would be allayed. If one could not answer satisfactorily then of course one would not be able to clear something as safe for release.

(*Professor James*) If I may come in, let us take the fish gene, which I am afraid I did not know of but Andy Chesson would doubtless. If that introduces an anti-freeze component I think that it is proper that in a committee one should look at the dimensions of what that might signify and one should think of all sorts of different areas of concern that might arise. You need to sit in on some of our British committees, where we run around with all sorts of crazy ideas before saying "okay, that does not seem to be an issue". I think we need more of that but done in a reassuring and involved stakeholder context. Then we will begin to make better progress.

Lord Jopling

671. We have been talking this morning about the situation that meets us at the moment. Would you not agree that we are going to see a torrent of new developments in the years ahead? We are only scratching the surface of this. How are we going to cope?

(*Professor James*) I am not sure that I know the answer. I think that one has to look at it piece by piece but, in addition, one needs to have the ability to pull

back and say, for example, on this issue about herbicides whether in fact there are going to be major impacts on the environment and so on. That is a very proper concern. There is a quantitative issue there as well as the specifics relating to each gene. I think it is very important that we have expert committees that are not just relating to the minutiae of a genetic modification but are dealing with the broader issue. If a torrent of genetic manipulations is on the way are there special questions that we need to think of now by virtue of having a multiplicity of changes in that particular sector of plants, or indeed animals? I think the GMO changes in terms of animals are likely to be much slower because of the huge antagonism to major changes in animals as distinct from plants. That is the view that we had in the Novel Foods Committee. We took on the public dimension of concern and therefore did not allow, for example, various gene manipulations to enter the food chain even though it had been shown that the genetic construct had not gone into the animal. We were so concerned that people would feel outraged by the idea of eating an animal which had been subjected to genetic manipulation. Although the ethics expert on our committee said that putting a human gene into an animal is ethically entirely appropriate, I and many other members of the committee thought that might be correct in strict almost legalistic ethical terms but one had to deal in a societal context with people's understanding. I think that we need this interactive debate. It is not a question of persuading people that everything is all right. It is a question of moving forward, if possible on a consensual basis. We cannot do that unless we do take the broader view as well as dealing with the specifics of each singular gene.

Baroness Young of Old Scone

672. I wonder if I can just take you back briefly to the precautionary principle and the concerns that it should not be interpreted as not being able to make any movement forward unless everything is known, because I would accept that not everything can always be known. I wonder if you could just describe whether you think it is possible to combine the precautionary principle with an adequate assessment of the scale of risks so that you get a feel for occasions when the scale of risk is sufficient that you do want to take a more precautionary approach and occasions when the scale of risk is less.

(*Professor James*) Thank you for a very penetrating question. One of the groups that I am involved with in Brussels is dealing with exactly that and that is the discussion that I had with the former CMO, Ken Calman: how do you begin to put a new dimension on risk analysis? There was a Treasury report on this last year as to how you look at the risk in environmental risk, human health risk and so on. I think that what has come through to me in the last year's struggle on the BSE risk is that we really have to move into a new dimension of understanding and start to express risk in a more meaningful way, not simply for the purpose of communication but for understanding. For example, the Health and Safety

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[Baroness Young of Old Scone *Contd*]

Executive perceives that if you are in the oil, mining or nuclear industry crudely speaking one in a million risk is the threshold for acceptable risk. People employed in that industry know that they benefit from that industry and the trade unions and everybody involved thinks that one in a million is reasonable. As I said to the Scientific Steering Committee in Brussels last week, that means that in Britain we should "allow" 50 cases of new variant CJD to be running as a routine per year in Britain. That is of course unacceptable. It is unacceptable because we are in a different dimension, because the whole society is exposed and they did not make the choices and see any selective benefits and so on. I think we are actually going to have to think through in a new way an integrated view of risk and set it out in a more explicit way and involving stakeholders. Then we can come to a judgment, and an explicit judgment, about the risk. Traditionally in Britain we have taken a completely different view from the United States on risk. In the United States they have gone down the quantitative analytical

approach whereas in Britain a group of experts have decided that, on balance, something is acceptable. I think by virtue of all the anxieties about food in Europe we are going to have to go much more down the American route of being more explicit, more analytical, more effective at communicating relative risks and better at demonstrating why we are making judgments in these different dimensions. Until then we are going to be challenged to use the precautionary principle on the basis that we are making all sorts of judgments with so little evidence at hand. I am not giving you a straight answer but I do believe that in trying to cope with risk we ourselves as scientists are going to have to go into a new dimension of thinking and analysis which some of us have not coped with terribly well hitherto.

Chairman: I think that brings us to the end of the questions that we wanted to ask you. Professor James, Dr Chesson, thank you both very much indeed, on behalf of the Committee, for having come and given us extremely interesting and helpful evidence. Thank you.

WEDNESDAY 4 NOVEMBER 1998

Present:

Gallacher, L.
Gisborough, L.
Grantchester, L.
Jopling, L.
Moran, L.

Rathcavan, L.
Reay, L. (Chairman)
Redesdale, L.
Wade of Chorlton, L.
Willoughby de Broke, L.

Examination of witnesses

PROFESSOR JANET BAINBRIDGE, Director of the School of Science and Technology, University of Teesside and Chairman of the Advisory Committee on Novel Foods and Processes, called in and examined.

Chairman: Good morning, Professor Bainbridge. Welcome to Sub-Committee D which, as you know, is conducting an inquiry into the EC regulation of genetic modification in agriculture and you are our last witness. We are very grateful to you for coming to help us and give us the benefit of your expert opinion and experience.

Lord Jopling

673. Professor, I wonder if you would explain how your Committee considers applications to market a GM food under the terms of the Novel Foods Regulation and whether in particular you assess every GM food or only those which are substantially different from those which have already had an approval?

(*Professor Bainbridge*) Certainly, my Lords. This question is actually the crux of the work that we do in the Committee so, with your permission, I will answer the question in some detail. Please interrupt if I am talking too much. Quite clearly all novel foods are assessed in accordance with the Commission guidelines which accompany novel food regulation. These guidelines follow a very detailed decision tree approach and are very much modelled on the guidelines that were developed way back in 1994 by the Advisory Committee which I chair. I do have a hard copy that I can leave for your Lordships of the 1994 annual report which has copy within it of that decision tree. I have to say at this stage that I have only taken over the chairmanship of the Committee some 15 months ago and have to acknowledge a tremendous debt of gratitude to my predecessor, Professor Derek Burke, who was very much involved in the work which led to the publication of those guidelines. Those guidelines were developed after a great deal of public consultation which took on board consumer groups and a whole range of consultation activities. For genetically modified foods the safety assessment, as your Lordships know, is based on substantial equivalence. That really means that we recognise that traditional food safety assessment techniques which tend to be based very much on toxicological data may not necessarily be applicable in the case of foods that are produced by biotechnology. This problem was highlighted by the FAO and the WHO way back in 1990 and they held a consultation

and identified the so-called comparative principle whereby foods assessed are compared with another that has an accepted level of safety. In 1991 the OECD expanded on that principle and formulated the idea of substantial equivalence which is very much part of our every day language today and a concept that we use very much. The concept of substantial equivalence codifies the idea that if a food or ingredient under consideration can be shown to be essentially equivalent in composition to an existing food or food ingredient then it can be assumed that the new food is safe. In other words, as I say, we are comparing directly a GM food with a conventional equivalent. The concept has been refined over the years since 1991. There was a major European conference in 1996 in Rome. The report of that conference quite clearly identified substantial equivalence as being established by a demonstration of the characteristics assessed for the GM organism or a specific food product derived therefrom (and I think that is very important) being equivalent to the same characteristics in the conventional comparator. The levels and variation for characteristics in a GM organism must obviously be within the natural range of variation (because there always is a range within natural organisms) for those characteristics which are being considered and based on appropriate and accurate and true analysis of the data. To move on somewhat, we are now working under the new European Regulation 258/97 and, under that food regulation, for applications submitted by the UK to the competent authority (or any other competent authority within Europe) the competent authority has 90 days to provide the initial safety assessment. This assessment obviously includes that the food is safe for consumption. It may conclude that more data is required. It may be that the food is not approved. Obviously the submission is at the same time copied to the Member States and the remaining Member States have a further 60 days to comment or object to the competent authority (the UK in our case). I should stress to your Lordships that all GM foods are assessed, including those such as refined oil from oil seed rape, which in composition are totally (100 per cent) identical to the non-GM food. The ACNFP as I have said has developed guidelines for deciding which if any of the food could be considered under the novel regulation for the so-called fast track procedure, the

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[Lord Jopling *Contd*]

60-day procedure. We have decided in committee that the only foods that can go through the so-called rapid route, the fast track procedure, are those in which there is neither novel protein nor novel DNA present. I should stress to your Lordships that we are erring constantly on the side of caution; that is very important. Perhaps I could give your Lordships one example that is in the public domain and is actually in the 1997 annual report. In there you will see evidence that we looked at five lines from a genetically modified potato where the company was asking for the fast track approval route through substantial equivalence. The argument that was made was that the product was highly refined and in fact was being developed to be used for French fries and crisp manufacture, and that any DNA that was present would be degraded. In committee we discussed this at some length and after our deliberations we concluded that there would be DNA, possibly degraded, possibly not, there certainly would be denatured protein present in the product and therefore we did not approve those particular five lines as suitable for substantial equivalence. I cite that example to your Lordships just to emphasise the way the Committee's deliberations err if anything entirely on the side of caution. I apologise for such a long answer but I think it is a very important subject.

Lord Grantchester

674. I wonder if you would please enumerate the direct and indirect effects that ACNFP takes into account when considering the safety of a food or feed. Perhaps you would elaborate on the cross references or databases you use to build up a picture of the individual application.

A. The safety assessment takes into account not only intentional changes that result from modification but any other unintentional changes that may occur, for instance, changes in levels of key nutrients, natural toxicants, and in particular—and I know this is very important—the level of potential allergens, the allergenic potential, of any new proteins. Obviously, in consideration of these things it is very important to draw on any information that we have available. There are databases. For instance, if we are looking at the source of the gene and the protein sequence we can compare against one database for example, SwissProt, which is a database of known allergens. We make substantial use of that. Again I should stress to your Lordships that in some cases the data simply is not available and therefore we have to extrapolate from the data and we have to look within our experience, and I should emphasise that within the 15 members of the Committee plus myself as Chair there is a vast range of different scientific experience to draw upon to look at these issues in detail. Sometimes the expected changes are deemed to be unpredictable but in fact they have been discussed in committee. If I can give you an example, one of the things about which there is very little controversy is genetically modified tomato purée. I will not at this point in time go through the advantages of that and the reasons why that product came into being and on to the shelves, but as a result of

that one unexpected effect was that the tomato absorbs during its growth less water, and obviously there are knock-on advantages in terms of cultivation and range of climatic conditions and so on, but I have seen it reported in the literature that it was a surprise (it was certainly no surprise to myself, because I am very much involved at the processing end, being a biochemical engineer) that, in fact, during the processing of that product (which is a process whereby water has to be removed; it is almost a condensation to make the purée) less energy was required because there was less water there in the first place. That is not a health effect I know but that is just an example of perhaps an unintentional change. I am sure it was not in the minds of the developers at the initial laboratory stage to produce a product that would be less energy intensive in terms of its processing but that was just a simple example of a knock-on effect.

Lord Gallacher

675. Professor Bainbridge, are you satisfied that GM foods are as safe as foods already on the market? How confident are you that GM foods will not have an unforeseen effect in the longer term?

A. This is obviously a crucial question and one which we must address with some competence if we are ever going to reassure the public and allay many of the fears that we hear about. Certainly in terms of the deliberations of the Committee it is absolutely crucial that we give very detailed consideration to the nature of the gene insert, its level, its location and expression, and, as I have already said, to the nutritional profile of the food, the composition of key toxicants. I have to say that our agricultural system is based on crops that over centuries in some cases (decades in others) are a result of natural mutations, strain selection, hybridisation, and in some cases we know very little about the genetic composition and stability—we are learning more all the time—of some of these key nutritional crops, so I am content that for the GM foods that have been approved not only do we have a much greater knowledge base but they are as safe as their non-GM counterparts. If I could address that question and to help to allay some of the public fears, the ACNFP is looking into the practicality of setting up a post market monitoring system. I should stress that this is not because we do not believe that what we are doing is stringent and rigorous and it is not because we do not believe in our results. It is because we are very well aware of the need to provide added consumer reassurance and in the unlikely event of any unforeseen effects being seen in the longer term then hopefully with that system in place we will be in a position to identify them and react accordingly. We have held some open meetings. We held one in March and we now have an agenda date in December of this year where we are going to make final recommendations that we will obviously pass on to Ministers in terms of setting up post market monitoring. I should add, because I think it is very important that your Lordships should be aware of this, that those meetings will be attended not only by the scientific experts but also by an invited audience from

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a range of interests representing consumer interests, retail interests and indeed the pressure group interests.

Lord Wade of Chorlton

676. Listening to how you have answered the questions so far, I get the impression from what you are saying that there is nothing inherently within the genetically modified structure that in itself can add any possible danger to a foodstuff.

A. Our principle is to err on the side of caution. We have only approved four types of GM product, as your Lordships know, that is, the chymosin, the tomato purée, soya and maize. We have received many applications that have not actually been given final clearance and I have to say that a great deal of concern is addressed at developments that are still very much at the laboratory stage. If these are developments that are food related they in due course will come to the Committee and be considered with due diligence and care and consideration, and there are obviously other aspects of concern that are being addressed. If your Lordships were to ask, "Can you give a 100 per cent guarantee of the safety of these foods?", I would be being deceitful and betraying science if I were to say "Yes, I can," because no food, conventional or GM, can be 100 per cent safe. Something that I quote quite frequently when I am talking to consumer groups is that if our common standard potato, totally non-GM—your King Edward or whatever variety it might be—were to come to the Committee today as a novel food (For we do deal with other novel foods apart from genetically modified foods.), given our regulations it would not be approved because, as your Lordships know, it goes green and it does produce certain toxins and we would look at that and would probably look at the level of those toxins and say "No, this is unacceptable." We err very much on the side of caution but we never can say, given the understanding that we have of risk and risk assessment, that any food is 100 per cent safe. If you talk about allergens, milk for instance, one of our staple foods, no-one would ever think about banning milk or saying milk is unsafe, but there are some people who are quite seriously affected by a milk allergy.

677. Does the GM element of a food that has a non-GM comparable food add any risk whatsoever that is not there in the inherent food? That is what I have been trying to get a feel for, how you respond to that concept, because some of the comments you have made have suggested that there is no difference at all, that you cannot find a difference between a GM product and a non-GM product when they are similar in other regards. How much added risk do you think a product acquires when it has a GM element compared to a similar product that does not have a GM element, or do you think there is any at all?

A. What you would need to do is to say, "What is added?" You would look at the genes that are added that are not natural genes to that food, ie the novel gene, and you would say, "That might be a gene that is present elsewhere but it is novel to this particular food product", and then you would look at it in the

context of the total genome of the food, you would look at how that gene is expressed, in other words what that gene actually does, and if that gene for instance is producing a protein you would look at the structure of that protein and you would look at that protein and say, "Does it match anything that is in any database for allergens? Does it confer upon that particular food the ability to produce a new toxin? Does it confer anything upon that particular food that could have some environmental effect?" and so on, and then you would look at that insert each time on a case by case basis.

Lord Gisborough

678. Professor, have you so far had any foods through you where you have not said that you want more time but have actually said, "No, no, no; do not come back"?

A. In my short experience, no. Things that we have not approved have been not approved because we have said, "No, it is not suitable for the fast track; provide more data", or because we have asked further questions. If you were to say are there some things where I could sit here and say, "No, no, no", I could. Certainly I have heard of things that are going on in the laboratory, perhaps not in the UK, and I would say no. I do not at this point in time see that there is any advantage in some reported gene transfers, but that is me talking as a layman. That is not me talking as the Chair of the Committee.

Lord Grantchester

679. We have received evidence from some plant breeders and they have seen developments in plant breeding as a continuum with genetic modification at the extreme end. I wonder if you would like to comment on that view of plant breeding because what was expressed to us was that there were several technologies, such as hybridisation, that could lead to novel foods, and that genetic modification was by no means the only way to produce a novel food. Could any more orthodox plant breeding technologies theoretically escape the net because they do not come under the banner of genetic modification?

A. First of all I would perhaps refute the statement that genetic modification is the extreme end because it is simply an intervention but the final product is not doing anything that could not happen anyway naturally. As I have said before, it is controlled in that it is deliberate and we understand which genes are being transferred, how they are being transferred, how they are being inserted, and we know a lot about their behaviour once they are inserted. The beauty of that as a technology is that it is directed and it is much more rapid. I do have some concerns about techniques whereby chemical mutagenesis for instance is used and there is no mechanism for controlling what goes on in the genome. I also have some concerns about some technologies not to produce GM foods necessarily but for instance there was an article today in *The Times*, about the so-called "terminator" technology, and again that could be seen to be

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applicable only for commercial gain. There still are a great number of issues that are not really the remit of the Committee but they are issues that in the broader sense are very necessary in terms of this technology and indeed all plant breeding technologies which are connected with intellectual property rights, patenting etc. There needs to be a great deal of clarification of many of these issues. I hope that has answered the question.

680. In your Committee you are confident that there are not any other technologies which perhaps avoid coming before your Committee. Would the fact that they are novel foods by itself mean that they would come before your Committee?

A. The technology might not come before the Committee if it is not to produce a novel food but if the technology produces a novel food, it does not matter how it is produced, be it GM or any other technology, it would come before the Committee. Indeed, a food which has been part of the food chain elsewhere in the world—there are very few of them left—not the type of food supply chain that we have but something that had not been a substantial part of the UK diet or the European diet, should I say, would have to go before the Committee. We are not just looking at foods for new purposes, we are not just looking at GM foods. We are looking at a range of foods that are novel to the UK. A novel technology, as indeed you speculate about, producing a food product: we would look at that food product and obviously part of that examination would be to look back at how the technology obtains that, at how the product was derived from the laboratory bench through the field through to the food product.

Lord Jopling

681. Professor, I wonder if I might illustrate the point I want to make by quoting a short bit from the current *New Scientist* which says, talking about genetic modification: This is not an extension of classical breeding. In classical breeding it is possible to cross relatives to create hybrids. You can cross a donkey and a horse and get a mule. But you cannot cross a donkey and an oak tree. With genetic engineering technology can cross all the biological boundaries. You can make mice with human growth genes and you can have firefly genes lighting up tobacco plants. The question I want to ask is: do you think there is something that gives inherently added danger if you step beyond the limits of classical breeding? Do you think, once you have stepped over that and started crossing donkeys and oak trees, there is some new inherent factor in that process which ought to make us more cautious?

A. First, there are a thousand and one articles where this very issue is raised and they usually start by quoting animal examples which are obviously very emotive. Having said that, when we are talking for instance about pharmaceutical use the technology is much more accepted, so there really are two issues anyway. I will try and answer the question with reference to food. It does not matter in one sense where

the gene comes from. It is how the gene behaves when it is inserted into the product that is going to hit the market place. What we have to look at is how can we protect the consumer? As I tried to articulate, by going through the decision tree approach and by analysing the data step by step all possible scenarios—what if, what if, could this happen, and so on—we try and ensure that we have got as close as we can be to absolute safety. As I have already said to your Lordships I cannot sit here and say I am happy or confident that there is 100 per cent safety because I could not say that about any food product. There are however inherent dangers in taking the technology too far. There are issues again that are outside the remit of the Committee that should perhaps be within the remit of a much broader biotechnology committee, about approval of the experiments in the first place, is it wise to go along this route? There is a great deal of controversy, if I could give you an example, about taking fish genes (fish, because they are cold-blooded and they have particular genes that give them the propensity to survive in cold climates) and introducing those into plants so that you can increase the agronomic practice and plants effectively become frost resistant when they were not before and so on. There is a great deal of concern because the technology would be seen to be transporting an allergen into a plant. Therein lies the message. We have to look at each example on the case by case basis, look from where the gene comes, where it is going and how it will be expressed and what it will do. I have to say that again what is or what is not approved on a laboratory scale is not really the remit of the Committee. As a scientist and as someone who is active in biotechnology in the much more generic sense I have very clear opinions but I would not like to confuse your Lordships in the sense that I am trying to clarify when I am speaking as Chair of ACNFP and when I am giving you my personal opinion. You are right: there is a great deal of concern and we do need to reassure the public at all stages through the regulatory process.

682. Speaking for myself, I would be most intrigued to hear your personal opinion.

A. There is a great deal of commonality in the genome. We all have our own individual genes. There is a great deal of basic commonality in nature. The genetic code applies from the simplest prokaryotic organism right through to man, if we can indeed put ourselves at the top of the evolutionary tree. I sometimes have my doubts. There is a commonality in genes so it is sometimes not so spectacular to say we will take this gene from A to B, could this be terrible?

Lord Wade of Chorlton

683. What you are saying is that although a donkey and an oak tree are different, it is the combination of genes that make the difference and not the individual genes in either a donkey or an oak tree. Is that it?

A. Yes. It is more than just the combination. It is how the gene is expressed and what it does when it is

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in its new location if you like. Through the medium of genetic modification we can in the laboratory do things that would not happen because of the laws of nature in terms of breeding that would not happen naturally.

Lord Moran

684. I was not clear about one aspect of your original answer to Lord Jopling because at the beginning you said that it did not matter where the gene came from. What mattered was how it behaved in the organism you put it into. Then later on in your answer you said there was a great deal of concern about various things including where the gene came from. I was not clear whether in fact your view that it does not matter covers all aspects.

A. No, it certainly does not. Perhaps again I can illustrate that by giving you an example of something which your Lordships may refer to later. It does matter in a sense not so much where it comes from but what it actually does when it is inserted. Obviously we have paid a great deal of attention to genes that confer antibiotic resistance for instance. In a sense perhaps it is not accurate to say it does not matter. It would be much more precise to say that we must look at everything on a case by case basis and the crucial thing is how the gene behaves, in our case, talking of novel foods, in the food or food product used for its intended use.

685. I would like to ask a question about what I think are known as "new genes". How sure are you that you can predict a gene's activity when it does not have a proven history of food use? Do genes without that history of food use present particular problems to you? Have any products containing such genes been presented to your Committee?

A. Most of the genes that are being inserted into food crops at present already have a history of food use. Obviously, in making an assessment of safety of proteins as they are expressed by novel genes it is very important for us to consider what previous human exposure there has been to such proteins. All such considerations are set out in detail in the guidelines that accompany the Novel Food Regulations and I do have (and again will leave for your Lordships) copies of the guidelines and also copies of the electronic database that your Lordships can refer to. Indeed that is provided to all potential applicants as well, so we try to make the process extremely transparent and as user friendly as we can. To answer your detailed question, a if a gene product (and I stress "gene product" rather than "gene" per se) does not have a history of consumption, then obviously we require the appropriate information. This will include toxicological studies, studies on mutagenicity, information on stability, and so on, on a case by case basis. At the moment we have not been presented with anything at committee where there are non-food genes incorporated into the food. We are at the moment looking much more at genes that exist being transferred from a prokaryote into a food or from elsewhere. The crucial thing therein is that as we get experience of working with the Novel Food

Regulation, as indeed we get more experience as more and more GM foods come to market in Europe and indeed around the world, it is crucial that the appropriate databases are set up where they do not exist and are accessed where they do exist. This is absolutely crucial because it is impractical and unrealistic if and when the technology picks up in speed and advances for every single case to re-invent the wheel as it were and where the data is out there we must make sure that we access that data and use it and apply it to the particular food product that is under consideration.

686. What precisely is a gene product as opposed to a gene?

A. The gene is the DNA. It is the sequence of bases. The gene product is the protein that that gene would express. That could be an enzyme, it could be a food protein or whatever.

Lord Gisborough

687. Just as you can mix two soft metals and get a hard one as a result, to what extent would it be possible to have two benign genes which collectively then became toxic?

A. That indeed is a possibility and this is why we look at toxicity very carefully. There is a gene that is naturally in the non-manipulated product and a new gene comes in, a novel gene is inserted into it, and those two together (you do not necessarily have to transfer two genes) could have a toxicological effect, so it is very important that we do look at toxicological data very carefully. In that context, as your Lordships know, there is the COT, the Committee on Toxicity, and there is cross-membership. The Chair of that Committee is a member of ACNFP and we do occasionally, when we are not satisfied with the explanation in terms of the toxicological data or where we require more, would refer a submission from ACNFP to that Committee. We each have a quite clear remit: and theirs is to look at this or that toxicological aspect.

Lord Rathcavan

688. Professor, you mentioned fish genes being used in plants. Could you develop that and explain to us what role you think this might have in the future?

A. I will develop that. These things have not come to Committee so I will not develop it in the sense of speaking on behalf of the Committee. As a scientist I will try and develop those arguments. It is quite crucial if we are going to feed the growing world population that we can extend the range of crops, not only the one that I referred to previously but being able to grow crops with an extra harvest a year or increase the latitude at which a crop can grow because it becomes frost resistant, but it is also crucial that we can grow for instance crops in arid regions of the world and so on. This is very much in the minds and eyes of those companies that are developing the technology and very much, I should say, involved in the sense of the blue skies research that is being done in academic

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establishments. That research is not being done in a haphazard way. Those experiments are all conducted after thorough scrutiny and approval through the appropriate sources. I think that work will continue. I think much of the work is blue skies and much of it will never see commercial fruition. As and when that particular product that has been developed in that way with one of these genes comes to the Committee it will come with a very detailed dossier of information and we will look at it, as we do now, on a case by case basis. When I said it does not matter where the genes come from, I do not mean that and I will not reiterate that but in a sense it is not so much the origin of the gene. It is how that gene is expressed and what happens. It is not the remit of the Committee to take on board the whole gamut of the ethics and the whole range of genetic manipulation. I have to say however that we never lose sight of ethical considerations. We do have on the Committee an ethicist. At the moment it is Dr Michael Rice who is also a scientist but very much involved in the ethical debate. Certainly in terms of the Committee's deliberations it is not a question of our having our scientific debate and then saying, "Over to you, Mr Ethicist", or, "Over to you, consumer adviser. What have you got to say?" Our ethicist and our consumer representative take a very active role in the Committee's deliberations. To that end it is quite difficult when we are appointing people to those posts in the Committee to find someone appropriate because we have to have someone that can participate in the scientific debate but also, as I say, represent the ethical viewpoint and we always are very aware of that. At the end of the day it is only with this attention to detail, this stringency of debate, that we are going to win consumer confidence.

Lord Wade of Chorlton

689. You have already mentioned allergenetics. Is more research needed on allergenicity as suggested by the recent Royal Society statement? Is this the only area which requires further research, or are there others which you believe may be problematic?

A. It is not the only area that needs further research and I will come back to some of the others. I will answer the question in terms of allergenicity first. The issue of allergenic potential is one that the Committee takes extremely seriously. It is a fascinating issue. I am confident that the procedures we follow as far as we can enable us to identify potent allergens. However, and this is very important, we have to recognise that there is always going to be someone somewhere that is allergic to something in food and maybe that allergy might arise for no apparent reason in that individual. There is a need to further refine the tools if you like that are available for identifying allergens. As an aside, there is also a need to further carry out the medical side of allergy, why do people become allergic. MAFF is funding work in this area to underpin the safety assessment procedures. The issue was raised for instance when we had one of our joint meetings with COMA, the Committee on Medical Aspects, and Dr Stephen Strobel, who is an expert on allergenicity, pointed out to that meeting that 50 years

ago when peanuts were not part of the food chain there were no peanut allergies, at least not recorded. Ten years ago when the kiwi was not part of the European food chain there were no allergies to the kiwi. We are now very concerned for instance as a nation about peanut allergy. It is interesting that in Korea the weaning diet for infants is actually mashed peanuts and in that country there is no known recorded peanut allergy. I am trying to give your Lordships a feel for the importance of the work and it is a fascinating area and a crucial one that we always try to address. The problem—and we have to be very sure that we can address this in any way we can—is that the allergenic potential (and I have tried to bring this out in the case of peanuts for instance) may only be apparent after several years. We have to estimate whether it is a one-off case because, as I say, there always will be people allergic to the other thing, or whether it is becoming a serious problem that ultimately will affect the health of individuals and perhaps in a wider sense. The only answer to that are the mechanisms that we are involved in now in setting up in terms of long term monitoring, long term surveillance of these foods. As part of the research that MAFF is commissioning they are developing an animal model for allergic response and allergenicity. I have to say that the research is not easy; it is not straightforward. I could perhaps quote an example of a test being developed. If a test were developed and 14 test sera were developed for potential allergens (much like the serum test that we do when people do have an allergic response) and if all 14 prove to be negative, it is still not possible within the laws of binomial statistics and the laws of mathematics to say that that is 100 per cent guarantee that there will be no allergenicity. That still only gives 95 per cent confidence limits. The problems are very difficult. Obviously, if you happen to be the individual that has an allergy to peanuts for instance, peanuts not being a GM food—I do not want to muddle the debate but an allergy that people are well aware of—it is absolutely crucial. You do not want a 95 per cent confidence limit. You want to be 100 per cent sure of the safety, in the case of peanuts, that peanuts are absent. There is something else that I often say in terms of public interface and trying to explain things to consumers. When the public sometimes has to grasp, why bother with GM for food use, is it actually necessary, I often say that one of the things that will make the technology come of age (this is still very much at the laboratory developmental stage) is developing a peanut genetically that is non-allergenic. That is in the laboratory. I do not know; it is impossible to say. Some people say five years, some people say 10 years before that would be developed, so it would come to the Committee before it hit the market place. That I think will go some way to turn the whole debate around in terms of GM food.

690. That would imply then that you must know what it is in the peanut that causes the allergy amongst certain people who eat it.

A. They are starting to identify it, and I am saying that if we knew that, the technology would not be five

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or 10 years around the corner; it would be maybe a year or 18 months around the corner.

691. At this stage you do not know?

A. At this stage that is part of the process that we are doing. I also have to say that the famous case, the Brazil nut case, is a clear example where the problem was identified early on, and it was not a UK issue anyway, but that is something that would be identified and we have learned a great deal from that. For instance, once you have identified gene sequences that produce proteins that are allergenic, there are a lot of sophisticated things that can be done. You cannot remove the sequence because you would remove the protein entirely but you could turn the genes round back to front so that they are not translated and that might remove the allergenic potential. There is a lot that can be done. I agree with the Royal Society report. There is more research that needs to be done, and indeed MAFF is at the moment commissioning some research. I do not think that is the full story. There is an awful lot, not only the genetic type of research but also a vast amount of medical research, that needs to be done in terms of the human physiology and allergies.

692. You mentioned that you might have some thoughts on the other issues that might be problems that you might look at. Are there issues other than allergenic issues which you feel need more research?

A. Issues that need more research are mainly concerned with surveillance. There are a great number of issues—and again I am speaking outside my remit in one sense—which have been identified by DETR concerned with the growing of many of these plants in the field, issues of herbicide resistance, separation distances. Many of those issues are requiring more research and indeed that research is being undertaken. Many of these issues emphasise the importance of perhaps I could say a holistic approach. We have the range of food advisory committees. I have already mentioned COMA fairly extensively. I have already mentioned the Committee on Toxicity. I have mentioned ACRE. There is a wide range. What is absolutely crucial is to step back and I would like to step back. It is useful in a sense being a part-time Chair of a Committee. It is not my paid job because I go back to a much wider view of biotechnology. Indeed, I run a faculty that covers just about every aspect of science and engineering that a university faculty could cover. I would like to step back and say, "Look; there are broad issues" and I know there is some concern about those broader issues later on.

Lord Willoughby de Broke

693. Professor Bainbridge, earlier on you mentioned antibiotic resistance. I would like to ask about that if I may. Your Committee in 1996 recommended that, in general, antibiotic resistance genes should not be used and, in particular, those with bacterial regulatory sequences were considered inadvisable. Has your Committee modified its views in the light of the EC Scientific Committee's decision to approve the release of the ampicillin-resistance maize?

A. The short answer to that is emphatically no, it has not. If I could elaborate on that, the ACNFP stands by the guidance that it issued and indeed published in 1994 and 1996 in the case of antibiotic resistance markers where it looks at the toxicity of the gene product. Obviously the clinical, including the veterinary, importance of the gene and the likelihood of transfer are the crucial issues. That is the likelihood of the transfer of the marker gene and its expression in gut organisms. Perhaps the next stage, whether it is then expressed into human cells, is an issue that is so remote but we still consider that. I see no reason why the Committee should alter its guidelines in the light of the EC Scientific Committee's decision on the Ciba-Geigy maize. In this instance the ACNFP was of the view that the risk, in this case it was an ampicillin gene and its associated regulatory sequence transferring to the gut bacterium, was very small but it was finite and we stand by that. Indeed, the European Committee accepted that the risk was small and finite, so in one sense we agreed totally. Where we disagreed was how we would implement that. I think it is evidence to your Lordships again that if we have to make a judgement, as we do (and we have to try and base that judgement on the best scientific evidence that we have available where that evidence simply is not there because we have to learn from experience and we are learning all the time), we would always err on the side of caution. I personally have some concern—this is speaking generically, not as a committee member; we all do, the public does—about the very widespread use of antibiotics in medicine and in agronomic practice which I know is controlled and controlled very carefully: another whole area of argument. If I could finish by referring to the technology, not the applications—we are focusing today obviously on the applications of the technology—the genetic modification, gene transfer techniques, that technology is moving on extremely rapidly. It is quite amazing, the pace of change. Issues that were discussed in 1994 and in 1996, even issues—and as I have said before I have only been the Chair for 15 months—that were pertinent 15 months ago are becoming less relevant, and I quote one member of my Committee who, when we were looking at a particular product with an ampicillin gene, said, "Why is it there? It is sloppy genetics." The practical techniques that allow us to transfer and to manipulate genes in a controlled way where we had to use in many cases in the past antibiotic resistance markers have improved, the science has moved on, and it is possible now either to use that marker and to excise it, to chop that bit and its product out of the modified gene, or indeed use a different technique to transfer the DNA. It is becoming less of a problem whilst all around us antibiotic resistance is becoming a major problem. We must in committee continue to re-focus on this and always apply our very precautionary approach in this context.

694. Are you aware at all—perhaps not in your Committee—that companies are aware of the concerns that there are different methods now which they would use in preference to using antibiotic marker genes?

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[Continued]

[Lord Willoughby de Broke *Contd*]

A. Absolutely. We do not have the responsibility of ensuring that the research and development arms of major multinational companies are up to date but it is obviously in their commercial interests that they are and in my experience they are very much and work very closely hand in hand with the universities. In some parts of this technology it is impossible to say who is further afield: the leading universities or the companies. Certainly the company that put a submission to the Committee (and, as I say, one of my colleagues referred to it as "sloppy genetics") are in no way unaware of the need to remove that gene because the submission simply was not approved and it went back worded in a somewhat more technical way than that but with a recommendation that things could be done with that particular product and should be done. Certainly part of the public exercise that I am very proactive in, in publicising the work of the Committee and the openness and the transparency approach, is to refer to antibiotic resistance and refer to the precautions that we do take and the way that this particular issue, if I were to put a hierarchy of issues, would be very close to the top at one point, is dropping now, not because of less importance but because of the way the technology is developing.

695. Are there any other genes or groups of genes which ACNFP would think it inadvisable to release?

A. There could be but again I have to say that what we would do is look at them on a case by case basis. I have mentioned mutagenicity and we would look at genes that might infer mutagenicity. I have mentioned stability, I have mentioned toxicity, I have mentioned allergenicity, so I think they are the key areas.

Lord Rathcavan

696. Are you saying that with the less sloppy genetics now available you should produce a maize without the disadvantages of this particular Bt maize?

A. That will come.

697. When is that going to come along?

A. The techniques are very complex and it is not possible at this point in time to say that it is impossible not to use any antibiotic resistance marker. It depends on the type of insert and the length and how it has been transferred. There is a whole range of technical issues there. Sometimes it is not possible to excise it without excising part of an express protein, but ultimately there is no reason why. Again it is in the future. We are not in a position to say, "This maize that has been approved should be withdrawn and now you can produce this one because it can be produced without an antibiotic resistance marker." We are not at that stage yet. It is not possible to do that. As the technology advances the companies are looking for new modifications, new inserts, for a whole host of reasons and I am sure in the future if I were asked, this would be one of the ways in which the technology and the means to producing the product would actually go.

Lord Redesdale

698. What is the relationship between ACRE and ACNFP?

A. Very good. We meet regularly. In fact, I met with John Beringer yesterday morning. We do have common membership and the secretariats work very closely together, which is very important given that they are reporting to two different Government departments, but they do. There is a great deal of interface and day to day exchange between the two secretariats. One other example of working together is that we are looking at arranging meetings of advisory committee chairs. I think it was last week or the week before that many of the advisory committee chairs met with Sir Robert May to see how we could best bring about this. There have also been joint meetings between ACNFP and ACRE but not in the past 15 months. I think relationships are very very good. With the emphasis that is placed at the moment upon the changing of the remit of ACRE somewhat and the current press releases from Michael Meacher, etcetera, I am sure that that good working relationship will continue and indeed be strengthened.

699. What environmental assessments are being conducted on GM foods in developing countries? Do you have any control over the multi-nationals?

A. For all viable GMOs used as food that come into the European system there is obviously a requirement to provide an environmental risk assessment similar to that required under Article 90/220. Where a crop is intended to be grown in Europe this risk assessment will be undertaken as part of the procedure for issuing marketing consent. If the crop is grown in America then there is the American FDA with their systems that are different but very much parallel to ours, but the control that we have over crops that are grown in developing countries really starts when the crop is imported into Europe and then it would come under the European regulation.

700. So are you saying that work could be carried out here and that the crop could be grown in a developed country with very little regulation? The only regulation that would happen is when that comes back as a food source within Europe, is it not?

A. Yes. I am going over my boundaries and going into that of ACRE. There are issues and there are recommendations being made and I am sure those recommendations will be widely dispersed throughout the world. In fact, ACRE is held in equally high esteem as ACNFP and they are looking at issues in terms of planting distances and effects on the countryside, etcetera, etcetera. In terms of what can we do politically here in the UK to control another country elsewhere in the world, it is a very big question and obviously as a simple scientist it is outside my remit and it is an issue of global politics.

701. Even if the work was undertaken here and then exported?

A. If the work was undertaken here it would be subject to our own safety and our own regulatory procedures. If it was simply work that needs to be exported because of the climatic conditions, e.g. we

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[Lord Redesdale *Contd*]

cannot grow bananas in the UK and so there would be a certain amount of control or advice there, but if you were asking me what we could do at the final regulatory stage, that is a major political question. It would not be a case of saying, "Here is the technology, get on and grow it", it would be accompanied with the appropriate advice.

Lord Moran

702. Could you tell us how you think the status and work of your Committee might be affected if the Food Standards Agency comes into being? From what we have heard it sounds as though it may be some years down the road before it is up and running. It would be operating in the same field as you are.

A. We have all heard that and obviously it is not protocol to make any detailed comments prior to the Queen delivering her speech. I am certainly unequivocal in my assertion that this is a major opportunity for us to instill consumer confidence and a major part of acceptance not just of GM foods, I hasten to add, but this is an attempt by the agency to bring things under one banner and perhaps engender an holistic approach. The White Paper was very explicit that the work of the ACNFP would continue. Indeed, I would hope that we would continue to earn the respect of peers and worldwide respect. The difference would simply be that rather than reporting to Ministers who make the decisions after taking our advice, we would report through the commissioners of the agency. I do think it would be a wonderful help to us in terms of allowing us to evidence our real concern for the consumers. There has been so much hype leading up to the formation of the agency. The show is on the road. Procedures and structures and things are obviously being developed and in a sense the secretariats of the committees are there and they will still operate and service the committees in the same way that they do. So it is not an issue affecting the Committee directly, I think it is much more an issue of consumer confidence.

Lord Grantchester

703. I wonder whether you would like to expand on your answer to Lord Redesdale's question about the fact that when food comes into this country you would require it to have undergone an environmental assessment. I just wonder whether this is always the case because when the Minister of Agriculture was here a few weeks ago I pressed him on whether there was a concern that products could come in through the back door as it were without undergoing the gamut of tests and standards required in this country. His response was, for example, that in the United States the environment was not a concern. I wonder whether you would like to comment on whether products and foodstuffs can come into this country without having undergone full testing and escape your Committee.

A. As I have said before, the whole area of the environmental assessment if it is not applied to a novel food is somewhat outside of my remit. If it were a food that had not been imported into the country

before, then indeed it would be a novel food and we would ask questions about the environmental assessment and obviously pass that on to ACRE. We do not have on the Committee agronomists, horticulturists and the sort of wealth of experience that we would need to answer in detail these sort of environmental questions. Any novel food would come before the Committee and part of our deliberations is to ensure that the appropriate environmental assessment has been carried out.

704. What is behind my question is the different regulatory standards that operate in the US and EC. I am trying to identify whether this is a problem.

A. I think you have identified where there is a potential problem and where further work needs to be done and where again not only do we need to take an holistic approach to the many food chain issues that there are, novel foods, environmental and a whole host of other considerations, but we need to take a global view because indeed the food chain is global. I was talking to the Food & Drink Federation and they were at pains to stress, which we know anyway, the global nature of their suppliers and indeed the disparate nature of their suppliers. They will buy particularly commodity crops from sources depending on the market price, etcetera. Taking a simplistic view, it is very very important that we are aware of that, but what we can do in a practical sense in the UK or the EU to control USA FDA decisions is limited in a sense, but what we must do is enter into dialogue and continue the dialogue because there are issues about crops that are sourced elsewhere.

705. Obviously it is of concern to the farmer if his competitors are able to grow products from seeds that have not yet been properly assessed within this country.

A. Absolutely, yes.

Lord Gisborough

706. Professor, how do you envisage keeping crops which have been engineered to produce active pharmaceuticals separate from crops grown to produce food?

A. This is actually a very important question and again I am not passing the buck but I will preface my answer by saying that it is the business of ACRE. From a scientific perspective, such crops will need to be kept isolated from food crops and we are concerned from the food end. Isolation distances, as I understand it and I could not quote specific ones, are already used as part of the seed certification process to ensure that the purity of a seed stock is good and specialist growers do have experience of growing so-called identity preserved non-GM crops, it may be for food use, it may be for industrial use, it may be for pharmaceutical uses. Recently SCIMAC have actually issued guidelines for commercial management of GM crops in the UK and perhaps this could form a future basis for separation of non-GM crops. I referred earlier to the fact that this is one area where there is more research going on and indeed more research needed. Questions arise like What sort of guarantee do you

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want? Is a 99.5 per cent guarantee that the crop is GM free sufficient? It is impossible to give a 100 per cent guarantee. Obviously I have referred to segregated planting. There are issues about segregation in terms of harvesting and segregated processing, very very major, very difficult issues. There are things that can be done genetically to render the pollen sterile or indeed plants with no pollen. You need to be aware of the nature of the crops themselves. Many of our crops, maize, sorghum I think is one, soya, sunflower, are hybrid crops where by definition you cannot save the seeds, etcetera. I understand that hybrid rice is being developed. Then there are some other much more controversial technologies. The article in the *Times* that I referred to earlier on this morning referred to "terminator technology". In a sense there are a whole host of arguments against it, but this is one case where terminator technology would actually remove the problem. There is often no simple answer because solving one problem might create three or four that could be as big or bigger. There are also other technologies like chloroplast genes. It is now possible to introduce genes into the chloroplast so that they are not expressed in the pollen and so there would not be the same sort of danger of transfer. Certainly from a UK point of view the only one where there is anywhere near consent in the near future is in terms of herbicide tolerant crops and the big problem in the UK, as your Lordships I am sure are aware, is with rape because of the way that pollen spreads over vast distances and the ease with which rape actually crosses and intercedes with some of our native weeds and other plants. That is trying to give you an holistic view. It is not my main area of expertise or indeed the Committee's remit.

707. There is considerable concern about the super weed. You mentioned that the pollen can be made sterile. Would that be the single answer to the danger of the super weed?

A. No, it would not be the single answer because it is not technically possible to do that in every case. Genetics is so complicated and it is not a case of you identify one gene and it has this one effect. Often there is a particular effect that you see. How much pollen is produced or the nature of the pollen grain or how it spreads or how and when it fertilises, etcetera is controlled by a whole host of different genes that influence different parts of the process. So it is a very very difficult technical problem. I raised it as something that perhaps has potential and it is being researched and it is worth looking at in much more detail.

Lord Rathcavan

708. Are you concerned that GM foods, which indeed may not be novel, may be unwittingly imported into the United Kingdom from countries where safety assessments are fairly rudimentary or lax or even non-existent?

A. Really the simple answer is that under the Novel Food Regulation all foods that contain GMOs or are derived from GMOs are classified as novel

foods and have to be approved before they can be sold in Europe. So the EU, and specifically the UK in this case, is not reliant on either rudimentary or non-existent safety assessments performed elsewhere in the world. We cannot shortcut the process and we need to be as cautious as possible. However, I explained to your Lordships that the Novel Food Regulation is very recent and we are seeing the first few cases coming through that system and we need some time to see how it operates and to sit back from it. At the moment the timespan is laid down in a very tight, very explicit fashion. We need to see how it operates. It looks at the moment as if there is a bit of a black hole in Brussels and the limiting factor is going to be the Scientific Committee for Food and how quickly that can deal with the backlog and how quickly that can turn things around. We also need time. We need time to be able to demonstrate and earn mutual respect. I have sat here telling you that I believe that the ACNFP is held in great esteem and indeed the regulation was based on the guidelines that the ACNFP and my predecessors and indeed the secretariat worked so hard to develop. Other countries have other competent authorities who work in various ways and we have to earn their respect and we have to see how they operate and we basically have to develop that sort of competence that comes from knowing one another and how we operate and a clarity of procedures, etcetera. In terms of the second part of your question about the actual efficiency of the process, I think it is too early to say, "Right, this is what we can do. Let us change this and let's change that." Let us work through more submissions under the Novel Food Regulation, let us record very carefully how it works operationally and let us look and see if there are indeed backlogs in Brussels and what can be done about them and then start to say, "Well, it is not efficient because this or that or the other has gone wrong". We certainly should not be seen to be taking shortcuts in the name of efficiency because we will be compromising our guiding principle of safety and the precautionary principle. It is very difficult to see what else could be done short of some generic European central committee. I doubt that that is round the corner in the near future.

Chairman

709. What is the process for bringing imported novel foods to your attention? Is it an obligation on the importer to notify you if it is an imported food?

A. If it is a novel non-GM food, that is right, there is an obligation. The GM foods normally come from the companies who were actually producing the novel insert or whatever it may be, but there would be an obligation on the importer to inform the Ministry through the normal system of trading and decisions would be made by the secretariat as to whether or not this was a novel food. I have referred to the information that the importer would need to work through and provide. It would come to the Committee.

710. Are you confident that all novel non-GM imported foods are brought to your attention as required?

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A. Obviously I see it when it reaches the Committee. It is difficult for me to comment generically on systems of trade and tariffs that are way outside of my experience, but having worked with the secretariat and with colleagues in MAFF, for instance, I have to say that I have respect and am in awe of their ability and their dedication to ensuring that the systems do operate effectively.

711. It has never become an issue.

A. That is right. There are obviously questions in terms of the regulatory system and the Laycott enforcement system, etcetera. Again this is where something like the Food Standards Agency would be so wonderful because in a sense what might be seen as disparate bits of activity across different government departments and across different committees could be seen under one banner.

712. It might be different in the future with imported novel GM foods. It might be less easy to know if foods that were GM modified were imported from third countries. Could a situation arise where you were not sure that all GM modified imported foods were being reported to you?

A. Short of saying that I could be at every port watching every cargo being unloaded, it would be impossible to be totally specific, but I have to say that provided—and it becomes a criminal matter if the law is being flouted—the regulations and indeed the letter of the law is being adhered to then I do have every confidence. I should add that it is not simply a case of importing a novel food *per se* but a food that might be used for a novel purpose. So some of the things that come to the Committee are not necessarily novel in that they have not been in the UK before but they are being used in a novel way.

Lord Gisborough

713. Is there any possibility that seeds might have come from GM plants which have been grown where there are no regulations and so we might be importing a seed which has got peculiar properties?

A. I hate to keep saying it is out of my remit, but I understand that there are very stringent procedures in the lead up to the stage where seeds are certified and I presume this would include details of the origin of the seed and the agronomic conditions under which it was grown, i.e. if there was a claim that it is an organic type, a natural type product, how close it is to being 100 per cent GM free, etcetera. So all that data would actually be included. There was a joint press statement by Michael Meacher and Jeff Rooker just last week in terms of the extra work that needs to be done to look at this area and people like English Nature and nature conservationist societies generally are actually addressing this problem in their statements in terms of pulling back from growing some of these GM things in the UK. Once you start talking globally, as in all things GM technology is not an exception in this, it becomes a matter of international diplomacy and international law and all sorts of areas such as import trades tariffs that are way outside my remit as a scientist.

Lord Gallacher

714. Professor Bainbridge, leaving out of the reckoning the Food Standards Agency, have you any thoughts on how we can maintain public confidence in the regulatory process for foods?

A. Yes. Part of my mission is to try and be very proactive in this respect. I think there are lots of things we can do. Certainly I see it as my role obviously to be completely independent. I do not see that as meaning I should not talk, for instance, to retailers, to food industry representatives, etcetera. At the end of the day everyone that is involved in food chain supply wants one thing and that is safe food. We need to get that message across to the general public loud and clear. I think there is a great deal of misunderstanding and there is a great deal of hype. It does not help that there are scientists—scientists disagree anyway, they are bound to in terms of some of the detailed arguments and it sounds very patronising to say to the general public, “Well, you wouldn’t understand, but I am just telling you I am right”, and I would not presume to do that, but there are those scientists that find it easier to make a name by being controversial than they do for their science and so we have to cope with all of these things. Many of the NGOs are of age now and there are people who have made a career out of protesting about various issues. Indeed, I think it is very very important as an independent committee that we should talk to these people and work through many of these issues and often by doing that we can identify possible ways forward. In terms of the transparency, there is clearly a move right across government for further transparency. My style is to be open and accessible and friendly. Since I have been Chair of the Committee we have asked for non-attributable minutes that are now published. 1991 was the first ACNFP Annual Report. We issue press releases. I am trying to be as receptive as I can to requests for media time and things like that. It is difficult when you do another job as well and you live at the other end of the country, but I think all these things help. It is a question of trying to be honest and open and not saying, “Oh, it is 100 per cent safe, don’t worry.” No, we cannot say that, but let us try and work through some of the issues and where we do have a problem, where we do need more research—and you have articulated several areas this morning—let us be open and say that. I think all of these things will help consumer confidence. We are never going to win everyone over. I think it is quite important that people have the information in a form that they can understand and do have free choice. People have free choice now and it is increasingly so. For several years you have been able to go to the supermarket and buy conventional fruit and vegetables or pay a premium for organic ones. I am sure your Lordships are aware of the initiatives to make non-GM foods available in the supermarket. I can foresee a time when the standard food which will contain GM will be labelled accordingly and there will be non-GM products at a premium. We have a long way to go. We have a lot of issues to work through, analytical issues, regulatory issues, before we are at that stage, but I do see that as the way forward. I do not see it as part of my role as

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the Chair, metaphorically speaking, to push GM foods down everyone's throats. I think it is important to say they are here, they are a fact of life, but these are the regulatory systems that we have in place. We do caution "But please spend your money and take your choice". I think that is absolutely vital.

715. Are you satisfied that the secretariat is PR minded?

A. I have enormous respect for the secretariat and I would not like to make any comment about whether anyone is PR minded or not. Obviously there are restrictions on civil servants in terms of things that they can and cannot say. This is the beauty of a system whereby committees have independent chairs. I obviously work very very closely with the secretariat. I ask the secretariat in many cases for information and I ask for support, I accept that, but at the end of the day I am not prepared to compromise my science or my knowledge for any particular viewpoint. I think my predecessor made a reference to his role as being a tightrope walker between the consumer on one side and government on the other and I think it is absolutely crucial for consumer confidence that people like myself are seen to be working very closely with government, but we are independent and I am free to speak my mind. I hope I am PR minded, but I do not think it is for me to say whether the secretariat are or not. I was enormously encouraged when I saw the plans for the agency and reference to the Communications Unit because it is my view that there are issues and there always will be issues and there will undoubtedly be further scares in a whole range of areas right across the food chain. It is very very important that they are handled correctly. There is no magic answer to that, otherwise some clever PR man would have made a fortune by saying this is the way to handle it. I do feel that Government has some way to go in terms of handling some of these issues. I am sure the Government is aware of that anyway. I think the Communications Unit—mind you, we are expecting a lot from it—is something that could be right up there in front in terms of the consumer. I am sure if we made our meetings completely open we would be flooded with observers and after a bit they would fall off because people would find it quite dry and boring. It is the media hype end that has got to be handled absolutely fairly and squarely.

Lord Willoughby de Broke

716. Professor, has your Committee had any thoughts on the merits or demerits of a moratorium on GMOs?

A. We have not discussed it in committee as a formal agenda item, but I certainly have very strong opinions and so I will give you my opinions and obviously they impinge on the workings of the Committee in a sense. My science goes back a long way pre-GM days. I did a lot of research at Durham when it was on mutation and strain selection and about that time there was a major conference in the States and there was the Asolomar conference and that led to a moratorium on GM work. Perhaps this is a bit of

an exaggeration and I have not got time to talk your Lordships through the history, but it fizzled out after a couple of years and it was felt quite clearly after public consultation that the scientists should monitor themselves and a framework was put up to allow that. I understand that at the moment a moratorium would be illegal anyway, but leaving that issue aside, I think it would be a disaster because I think it would be tantamount to saying, "We are not really sure so we had better step back and we had better stop this work, we had better stop the progress of the research and the development of the applications". I think at the end of the day we have to be minded about issues like industrial competitiveness and economic concerns. Even as an academic scientist you cannot be divorced from economics these days and certainly in my managerial role then perhaps the best training would be to be an accountant. If there were to be a moratorium, what good would it do? Where would it take us? It would allow us to step back, but it would do no more than that because you have to pick up from where you left off two years on, five years on and anyway, would it be a moratorium on growing the crops or on doing the laboratory work or selling food or would it be the lot? So there are some major issues there. What would be necessary to say that it could come to an end? You could not conceivably have it forever anyway. So what could trigger the end of the moratorium? And if you could not do any work I am baffled to say how the end would be triggered. There are a whole host of issues. In my opinion it would be worth no more than the paper it would be written on because you could not enforce it globally and we would be very wrong to assume that it is only in Europe and the States where with political will we might get some agreement if it was deemed that we should, but we would be very wrong to say these are the only countries where the work is going on anyway. So for a whole host of very real reasons I am totally opposed to a moratorium and I believe that that is the Government view as well.

Lord Rathcavan

717. You were talking about public confidence. Would not public confidence be improved and public awareness if there were more GM products in the market? You referred to tomato paste being the only experience the consumer can have of a direct GM product that is easy to compare with a non-GM product in price and quality. The concern is where there is an ingredient of soya flour. Looking into your crystal ball, what new pure GM products do you see coming on to the supermarket shelves like tomato paste?

A. I have to say that the majority of products that I see coming through are mainly commodity products. I have referred to some lines of potato for instance. They are not ready yet but they will come through. There are so many products from soya, the oils and things like that. I think the phrase nutraceuticals has been coined. There will always be changes to fatty acid profiles to make them much more preferable in terms of the problems with the UK diet and cholesterol,

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etcetera, etcetera and tailoring them, products with added vitamins and things like this. So I do not see many totally pure products coming through. There are undoubtedly vegetable crops, fruit crops being developed for enhanced yield and enhanced disease resistance. There is work being done on rice, etcetera. The ones that are causing concern are things like soya because you hear that in excess of 60 per cent of all processed food contains soya, but I would guess if I stood in the street and said, "What is lecithin?", most people would not know that there was a connection between that and soya. They might know the connection of soya oil by virtue of the name. Obviously if Sainsbury's and Safeway's, the two companies that sell the product, report enhanced sales of the GM product—and I do not believe it is just on price because certainly in the one of those two supermarkets where I shop the price is identical, it is just that the conventional tin of puree is 100 grams and the GM tin is 125, but unless you hold them side by side most people would be unaware of that. They are certainly very very clearly labelled.

Lord Moran

718. Could I follow up the question about labelling which you have just been talking about. I wondered if you could tell us what you think about the labelling of GM and GM contained foods. It seems to me that the whole point of labelling is to make it clear to the consumer that it does or does not contain a significant element of GM.

A. I agree with your Lordship on that assertion. You are right, the point of labelling is to make things clear to the consumer and when they have got clear information they can obviously make a choice. In my opinion in order to do that all GM foods should be labelled. Obviously I am aware that discussions are going on in Europe about the practicalities of thresholds, but it is these very difficult issues that we have to address when setting thresholds because you cannot say 100 per cent GM free below which labelling would not be required. When you are looking at a processed product that might contain soya, a pizza for instance, a very small proportion of that pizza would be soya flour and a proportion of that could be GM soya. How far down the line do you go? So the whole issue of thresholds is very important. I think we need to come to some agreement in Europe—and I know negotiations are underway—of a sensible way of ensuring that in as far as is reasonably practical a food labelled GM free means GM free, it means just that. As you know, there are GM free labels but it is not part of the official labelling legislation.

719. Have you a view yourself on what would be a sensible way of determining that threshold?

A. I think that we should set a minimum threshold. We should produce a negative list of products where there is no DNA or no protein present and that should be published. Refined soya oil is no different in any way, physical, chemical, nutritional or any other way, from refined soya whether it comes from GM or non-GM so therefore that should be part of the list.

Chairman

720. So that should not be labelled?

A. No, because there is no DNA or no protein present, but where there is DNA or protein present above a threshold—and this is subject to a great deal of scientific argument—it should be labelled. It is not just a question of setting the threshold, it is a question of ensuring that you have got the right analytical techniques and the right regulatory processes to police that threshold. It is one thing saying, "Yes, we have got all these wonderful analytical techniques where we can go down to a picomole level of protein, for instance, or we can go down to 0.001% DNA, that is fine", but if each test costs £80 and it takes three days in the laboratory it is no use as a regulatory tool for a poor trading standards officer or whoever who is trying to enforce the regulation. So until we have got agreement on the levels and then rapid, cheap, reliable testing where we know the degree of certainty of the result as well (because analytical testing is very difficult when you are not testing a pure product and you are not testing a pure product when you are testing a processed food) then there are a lot of issues. The generic point is that I think the thing should be labelled according to regulation whenever there is DNA or protein present. What about catering establishments? You can say the menu should be labelled. What about when you phone up and order a pizza? Should it be delivered with a label, by which time you have already ordered it? And what about the higher class catering establishments where the chef, who is probably a bit of a prima donna, might say, "There is not much gluten in this flour, I will shove an extra pinch of this in or put a few more bits of that in", how on earth could you accurately and sensibly label that? In my mind there are some very major issues, but certainly work is going on in terms of the thresholds.

721. The purpose of a threshold is to allow for the adventitious presence. That is the principle of it.

A. You have got to think of segregation at every stage in the food chain. Obviously many of these commodity crops are not only grown for food use and as you progressively go through more and more purification and more and more dilution of the GM crop the cost of segregation would be absolutely impossible. So you have got to allow for that adventitious contamination.

722. But the case of additives is different. An additive should be labelled in your view?

A. Additives and flavourings at the moment are not subject to the labelling regulation which came into force on the 1st September. I understand there are discussions going on in Europe because there are some concerns. Lecithin for instance, which is a soya derivative, it could well be from GM soya depending on the quantity, whether it was classed as an additive or not currently would not necessarily need to be labelled. I have to say that the retail trade, people like the Food and Drink Federation, the Institute of Grocery Distribution, have been labelling on a voluntary basis prior to the 1st September mandatory implementation of 1139 and are very very keen to

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clarify the labelling issues. I think there is a consumer issue. Many women, men as well to a certain extent, go to the supermarket and they look at the box and all they are really interested in, unless they have got a particular medical problem or interest, is the energy value, will it make them fat or not and then when they look at the energy value, in spite of the current SI units being kilojoules, they do not understand that, they just want kilocalories. That is the extent of the understanding even of something that is important to them. So we have got a very difficult balancing act because we want to label but without them understanding what the label is—you could almost envisage everything coming in a box with a long pull out with all the details of the labelling which is clearly ludicrous. So there are some major issues still around there.

723. But in your view should additives and flavourings be labelled?

A. Absolutely, yes. Unless we can say to the consumer that where there is a GM product, whether there is protein or whether it is DNA above this particular threshold—when that is agreed—then it will be labelled, then I do not think we are on the road to consumer confidence. When you say that there are rules about labelling but additives are not part of it or flavourings are not part of it then it does not really do anything to encourage consumer confidence in my opinion.

Lord Willoughby de Broke

724. Do you believe we need traceability as part of the monitoring arrangements for GM foods and how practical is the idea of traceability in GM foods?

A. It is not. There has been a lot of talk about traceability on the back of the BSE crisis and traceability to cattle. As I understand it, that has caused enough problems, although that is now being implemented. How do you trace a soya bean is a simple question. It is very very difficult. I think the approach to monitoring certainly that we are considering in ACNFP is not based on traceability but it is much more based on looking at the databases that we have and building on the existing capability of retailers to trace food products. They do have inherent traceability, they need to, in terms of a whole range of safety areas, for product recall for instance. It never ceases to amaze me when there is a problem how quickly the supermarkets can identify a particular batch or a particular production line or a particular supplier and actually recall them. So there is traceability in that sense. I think it is much more important in terms of the GM component, which is obviously where your question is focused, to go for monitoring and I have already referred to that. I have referred to the joint meetings and indeed the monitoring subgroup, representatives from the retailing groups and we have been enormously encouraged by their support and their willingness to help us and their willingness to provide data because there is a great deal of information out there. I have referred several times to the need for databases or the

need for more research, but it is also quite important that we do not reinvent the wheel. I heard someone say recently at the open meeting of the Food Advisory Committee, this is not in formal session but just in the corridor, we do not need any more people doing surveys on the street corner in Reading or wherever it might be, but what we want is people to start looking at the data that is already there. One major source of data obviously lies in the loyalty card schemes that many many retailers now have and we have been talking to the retailers. Obviously there are issues about confidentiality of data, but retailers are more than confident about sharing that data on trends and things and enabling us to use that data towards monitoring. So I think the message from ACNFP is monitoring rather than traceability but not forgetting the traceability that is available anyway through the retailers own systems.

Chairman

725. The post-market monitoring that you have referred to and which you are going to make recommendations on, are your recommendations going to include recommendations regarding who should be responsible for monitoring and what monitoring should consist of?

A. There are two generic issues. There is one about developing a system for monitoring and we have got to be confident that we have got a realistic and a meaningful system and at the same time that it is workable and then we have got to consider—and I suppose this is where it goes outside the remit of the Committee, this is for discussion by Members (of Parliament) and Ministers—how that is actually going to be undertaken. Obviously there are always throughout all these systems—maybe we can use an existing system in a slightly different way—financial and practical knock-on effects and we cannot divorce the financial cost. So we have got to make realistic recommendations because if we do not there will be questions like who bears the cost and is it right that it should be the taxpayer or the consumer and the sorts of questions that have been aired many times in terms of the Food Standards Agency for instance.

726. Do you see the monitoring as¹ being conducted by the companies in the private sector or by a government agency?

A. No. Again it is a question of consumer acceptance and I think the monitoring has got to be seen to be independent. I think the data obviously will come from the companies in the private sector, but how it is used I think is quite important and it has got to be used independently. There has been a great deal of talk about an over-arching committee, because it is not just the remit of any one of the advisory committees to which you have referred, we are all concerned with different aspects of monitoring. It should be either the over-arching committee or the agency, if and when the agency comes in.

727. So it could be something for the agency?

A. I think that would be the most likely location for the monitoring system because we have heard in

4 November 1998]

PROFESSOR JANET BAINBRIDGE

[Continued

[Chairman *Contd*]

the plans for the agency that it has made provisions for monitoring.

728. That brings us to the end of the questions that we wanted to ask you. Can I thank you, on behalf of the Committee, for the evidence you have given us. It

has really been extraordinarily helpful, interesting and clear and you have been with us for almost two hours. We really are immensely grateful to you. Thank you very much.

A. Thank you.

WRITTEN EVIDENCE

SUBMITTED TO THE EUROPEAN COMMUNITIES COMMITTEE (SUB-COMMITTEE D)

Memorandum by AgrEvo

AgrEvo informed the Committee that they were firmly in agreement with the position of EuropaBio (see pages 326–331) and the Green Industry Biotechnology Platform (GIBIP). They forwarded the position paper below to the Committee.

1. The Green Industry Biotechnology Platform (GIBIP), representing 20 European companies active in improving plant using biotechnology, welcomes the adaptation of the regulatory framework on modern biotechnology to the rapidly evolving scientific knowledge and increasing familiarity with biotechnology. It is of utmost importance that the regulatory framework provides for both the necessary safeguards for human health and the environment and enables the European society to fully benefit from biotechnology.

2. The Report on the Review of Directive 90/220/EEC (Com(96)630) issued by the Commission in December 1996, presented a good analysis of the functioning of the Directive, based on the experience gathered in the Member States following the first years of implementation. However, GIBIP believes that the current Commission Proposal on the Revision of Directive 90/220/EEC does not fully address the identified weaknesses of the current process. Furthermore, the Proposal introduces new provisions which add even further complexity. It is considered very important that the work of the EU Risk Assessment Working Group is revitalized, in order to harmonize Community risk assessment and to establish baseline criteria which are science-based.

GENERAL

3. To facilitate the practical implementation of the Directive, certain terms used such as “genetically modified organisms” or “placing on the market” require further clarification.

4. Clarification of the scope of the risk assessment is necessary to avoid duplication of safety review, e.g., with Dir.91/414/EEC or with the Novel Food Regulation.

5. Although other related legislation is being introduced (e.g. the Novel Foods and Novel Food Ingredients Regulation), the current Proposal does not make cross-references to this. It should clearly exempt those categories of products which are covered by other vertical (product) legislation as applicable.

PART B

6. Science-based legislation should foresee a mechanism for rapid adaptation to technical progresses. The current Proposal no longer provides for this regarding research and development activities.

7. The current Proposal brings substantial improvement to the procedure for research and development trials. The introduction of a multistate approval procedure should, however, also foresee different categories for genetically modified organisms according to familiarity and be further expanded so that review by one Member State only is required for a multistate trial (Article 6c).

PART C

8. A mechanism should be introduced whereby questions, comments and objections raised by Member States during the 60-day-review period and which fall outside of the scope of the Directive should be automatically rejected (Article 13).

9. The duration of the complete procedure for placing on the market is still not clearly defined, as critical steps (Regulatory Committee, Scientific Committees) remain without time-limitation. It is therefore questionable whether the amendments introduced for certain steps will improve the predictability of the duration of the process as compared to the current situation (Articles 20a and 21).

10. The Proposal does not address the non-compliance of the Member States regarding the specified time-lines.

11. The limitation of authorisations to 7 years is neither coherent with other legislation on genetically modified organisms (e.g., no time-limitation under the Novel Food Regulation), nor adapted to the reality of plant breeding and marketing. The proposed time-limit for authorisations under Directive 90/220/EEC should be withdrawn as it does not contribute to the safeguard of the environment or human health, but increases the development risk for the European biotechnology industry. In any event, the existing measures (Article 11 (6) or Article 16 of Directive 90/220/EEC) require notification of any new information concerning potential adverse effects and allow Member States to take safeguard measures, including product withdrawal. This also applies to previously authorised products (Articles 13b, 13c, 13d, and 22b).

12. Post-marketing product stewardship is common practice for companies. Mandatory monitoring as introduced in the Proposal should be related only to cases where potential risks have been identified during the

risk assessment under Directive 90/220. Monitoring will have to be based on sound scientific principles, criteria and protocols, related to these potential risk(s) (Article 13e).

13. The Proposal should provide clarity on the applicability, procedures and information requirements for the following categories of genetically modified plants (GMPs);

- GMPs used for processing but not for cultivation in the European Union;
- GMPs developed by combining previously authorised GMPs by traditional breeding methods;
- new uses of GMPs previously approved.

Where these products fall within the scope of the Directive, simplified procedures should apply.

14. Public involvement (availability of a summary of the dossier and publication of the Scientific Committee reports) will improve transparency. However, public consultation should start once the rapporteur Member State deems the dossier to be complete. The procedure for addressing public comments requires clarification (Article 17).

15. *GIBIP strongly believes that only a clear, transparent, timely and science-based regulatory framework, compatible with international legislation, will ensure environmental and human safety, while at the same time supporting the competitiveness of the European biotech industry and enhancing products acceptance.*

March 1998

Memorandum by the American Soybean Association

CREDENTIAL AND INTEREST

1. The United States is the world's major producer and exporter of soybeans, the principal world source of vegetable protein, and a major source of vegetable oils and other food products. At present, US area under soybeans lies at around 72 million acres, a figure which approximates to the combined land area of the United Kingdom and the Republic of Ireland.

2. In 1997, US production of soybeans reached a figure of some 75 million tonnes, mainly from states in the Mississippi basin, of which about 50 per cent will prove to have been exported, 15 per cent to Europe in the form either of whole beans or of soy meals produced after oil extraction.

3. The American Soybean Association (hereinafter "the ASA") headquartered in St Louis, Missouri, represents 32,000 producer members on national and international policy and issues important to all US growers of soy. Its commitment to international markets is attested by its thirteen international offices spread throughout the world, and by its ongoing promotion program for US soy products to a wide range of customers.

4. The ASA welcomes and appreciates the opportunity to contribute to the Sub-Committee's enquiry. The Sub-Committee will be aware that the US soybean sector in particular has been the focus of much attention in the European debate on the uses of biotechnology in agriculture. Criticism has been directed at it by European opponents of biotechnology, frequently founded on misinformation, and considerable confusion in Europe has resulted.

5. It is hoped that the present observations will open the way to a better understanding of what the US soybean farmer can do to meet the needs of his European customers in terms of securing product with the characteristics they require and are prepared to pay for.

GENERAL BACKGROUND

6. Soybean production in the US has grown from a near-zero base in the 1920s to current levels on foot of growing demand from the world food and feed industries. The climatic conditions in which it is carried on vary widely across the US, with 11 different identified climate patterns requiring different approaches to variety choice and to agronomic management.

7. The number of varieties cultivated runs into thousands, with seed provided by a range of large- and small-scale multipliers to suit local conditions. As with agricultural crops in general, there is an observable tendency in most cases for a soybean variety to peak in use and to decline over about a 25 year commercial life-cycle.

8. The genetic resource base is therefore in a constant state of development and renewal, and about a hundred new varieties obtained through classical selection procedures, enter commercial production each year.

9. With the development over the past 25 years of modern biotechnology, additional genetic options have become available to soybean producers. The advent of recombinant DNA technology has enabled improvements which have a favourable impact on agronomic practice, in terms of production costs, both of inputs and labour, in terms of farm health and safety, and in terms of good environmental practice.

10. The 1996 US planting season saw the first use of seed in the production of which recombinant DNA techniques were used to insert a specific agronomic trait into the genetic material of soybean seed of a number of varieties. The Monsanto Company had made available to seed multipliers the technology to incorporate into the genomes of soybean varieties an event which gives the soybean plant enhanced tolerance of the systemic herbicide glyphosate. It is estimated that the modification event is currently on offer in about two hundred varieties of soybean.

11. Commercial plantings of these beans, known commercially as "Roundup Ready" beans (or "RR beans"), only began after all existing regulatory requirements had been complied with both in the US and in major export markets for soybeans. To date, RR beans are the only transgenic soybeans in production that are exported from America, although authorization procedures are underway for several other modification events in the soybean.

12. In the European Union, the principal regulatory requirement was a decision authorising the clearance of such beans for deliberate release into the environment under Council Directive 90/220/EEC.

13. That decision (96/281/EC) was taken by the European Commission on 3 April 1996, following a favourable recommendation after detailed examination from the United Kingdom's competent authority for release of transgenic organisms into the environment, and a qualified majority in favour of such a decision from the member states of the EU meeting within the relevant committee.

14. In the first planting season, about 2 per cent of America's soybean acreage was planted to RR beans, with about 15 per cent in 1997, and about 40 per cent in 1998. The limiting factor on RR acreage for 1998 was the availability of seed, provision of which could not keep pace with demand. In future years, and as the RR technology is incorporated in soybean varieties of all maturity groups, it is expected that the technology will become the norm.

15. As neither the US nor EU regulatory authorities have seen any need to require separation of RR beans from other beans, the harvesting and marketing of all soybeans entering the bulk commodity system does not in general involve such separation.

16. This does not mean however that it is not possible to ensure that small quantities in container-sized lots can be supplied to order in response to specific customer requirements, but the costs involved would reflect the additional growing, handling and guarantee operations undertaken.

17. Hitherto, no standard specifications or form contracts to underpin such limited deliveries of non-transgenic beans have been elaborated, and the ASA has not been approached by any customers in Europe with a view to drafting them and recommending them to its membership.

SCOPE OF THE PRESENT OBSERVATIONS

18. The ASA would like to respond to the sub-committee's invitation specifically under the following heads:

- the appropriateness and efficacy of current regulation of novel foods and their labelling at European Union level (point 1(c) in the notice of invitation);
- the most appropriate jurisdictions (including international regulation and harmonisation) for decisions on genetically modified organisms (point 3 in the notice of invitation);

19. The ASA does not feel competent, in the present context, to comment on the UK's national approach to genetic modification in agriculture, and believes that the implications for soy arise essentially at EU level, something that may not be the case for other genetically-modified crops.

NOVEL FOODS AND THEIR LABELLING

20. In the ASA's view, the EU's provisions on novel food labelling have yet to be effectively applied or observed in operation. Apart from the basic novel foods regulation (258/97), no implementing regulation thereunder has been adopted, whether of a general nature or relating to a specific product. The system has yet to function.

21. The EU Council's adoption in late May of Regulation 1139/98, under the 1979 food labelling directive (79/112/EEC), on the exhaustion of a complex legislative procedure, merely targets those soybean and maize varieties which incorporate two specific proprietary modification events, and submits them, and products derived from them, to testing and labelling constraints in the name of consumer information.

22. In so doing, however, the Council has acted on an assumption, embodied in the sixteenth and eighteenth motivating grounds of the regulation, that both modification events render the products covered, and products derived from them, not equivalent to existing counterparts, on the grounds that there may be detectable variations in DNA and protein attributable to the events.

23. This would seem to do violence to the concept of substantial equivalence of novel foods as developed in the OECD and the WHO, which seeks to evaluate a novel food by comparing it with an established

counterpart, and determining whether there are additional safety concerns which need to be taken into account in the authorization of the novel food.

24. It may well be that the Council considers that the required labelling is unrelated to health and safety, and only addresses a consideration of consumer information. However, the ASA believes that this approach will give rise to conflict when it comes to establishing a sound international system for the control and management of biotechnology in agriculture.

VIEWS ON REGULATORY JURISDICTIONS

25. The ASA believes that the broad lines of areas of potential international disagreement on biotechnology in agriculture are already clear. They would seem to be:

- differing positions, perhaps of an ethical or social nature, unrelated to food safety and environmental protection, on the use to be made of transgenic plants in agriculture;
- the role of law and public authority in favouring or discouraging resort to transgenic plants;
- attempts to impede trade in and market access for transgenic plants using new policy considerations to justify new non-tariff barriers of a kind unacceptable within the WTO;
- serious divergence in approach to the authorization of individual products, whether founded on general evaluation principles, or on differing durations for completion of procedures.

26. The ASA believes that the WTO should remain the agency of choice for settling disputes in trade in transgenic products, albeit with the technical support and specialized advice of agencies such as the WHO (in particular through the Codex Alimentarius) and the OECD.

27. The ASA believes that the principles underlying the Agreement on the Application of Sanitary and Phytosanitary Measures, annexed to the 1994 Marrakesh Agreement establishing the WTO, offer the best existing framework to resolve differences which might arise.

28. The ASA would view with disquiet any suggestion that the Agreement, or any successor arrangement, should admit any public policy measures which, for reasons other than those based on sound science, would abridge the liberalisation of trade in farm products which has been achieved so far.

29. The ASA also feels that cooperation between regulatory authorities, founded perhaps on mutual recognition of approvals, would do much to eliminate difficulties in trade, where the pace of approvals differs between jurisdictions.

8 June 1998

Memorandum by the Austrian Embassy

1. APPRAISAL OF THE CURRENT DIRECTIVE 90/220/EEC

Austria wants GMO products not to disrupt broad social institutions and conventions ("Sozialverträglichkeit") and stresses the lack of knowledge on environmental effects through an emphasis on ecological data and ecological balance in Risk Assessment procedures. The approach to Risk Assessment is characterized by preventing adverse effects according to the state of the art in science and technology. Austria interprets the scope of directive 90/220 more broadly and also assesses agronomic effects, such as influences on the use of pesticides, to determine the acceptability of products.

2. PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING COUNCIL DIRECTIVE OF THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS.

The European Commission announced in its communication of December, 1996 on the review of directive 90/220/EEC(COM(96)630) to come with a proposal to amend this directive, which concerns the deliberate release of genetically modified organisms, during 1997. The Commission has made such a proposal in December 1997.

3. In general, Austria appreciates the EC's efforts to improve and adapt the directive according to scientific progress. In particular to include principles for risk assessment into the directive seems highly important, as this substantiates the precautionary principle and addresses one of the major weaknesses in the current directive and is expected to harmonise the risk assessment procedure throughout the Community.

4. For areas where no short or long term risks can be envisaged administrative procedures can be streamlined in order to benefit from the chances of modern biotechnology.

Control of products and regional specificity:

5. Consequently, modifications of the directive should only be done where they do not impose increased risks for the human health and the environment. As, furthermore, increasing amount of various products may be put on the market in the near future Austria welcomes the effort to address adequate ways of a control and monitoring of these products under the measures of directive 90/220. Furthermore, the improvement of the directive will have to take into account the highly different ecological situations and agricultural practices in the member states. Therefore, as part of a consent to specific products, the possibility for specific conditions which address the different biotic regions in Europe should be established as a provision.

Labelling

6. A coherent European Union approach for labelling of products produced from GMOs across the different sectors regulating the use of GMOs is supported. The new labelling requirements should provide clear, honest and neutral information about the GMO origin of products. With respect to segregation and the provision of labelling certain products with "*may contain GMOs*" we still have great problems with the proposed labelling regime, taking in particular account of the Decision of the Council of Ministers for Agriculture of 26 May concerning labelling of foodstuffs produced from genetically modified maize and soy beans.

7. The interplay with other Community legislation whether already in force or still under development (like Novel Seed or Novel Feed) will have to be made very clear and transparent. Following the adoption of the Novel Foods Regulation (258/97) the interplay between this Regulation and Directive 90/220/EEC has been the subject of interpretative documents by Commission services, indicating that some clarification still is required.

Comitology

8. The proposed change from a type 3a to type 3b procedure for the Regulatory Committee is welcome and is expected to raise public confidence in the decision procedure.

Transparency

9. We highly appreciate the endeavours of the Commission to establish confidence of consumers in modern biotechnology by the new provisions of the directive to make the EU decision-procedures more transparent for the public. A similar transparency should be established in the selection of experts for the scientific committees and on the way how opinions of the scientific committees are taken.

10. Concerning the Novel Food Regulation 258/1997 Austria regrets that clear uniform principles or guidelines to implement this regulation still are missing, as the legal text of the regulation raises a lot of interpretative questions.

11. Austria is of the opinion that any novel food produced from genetically modified organisms in which foreign generic material (DNA) or proteins (resulting from the genetical modification) can be detected by analytical methods has to be labelled accordingly in order to give consumer the free choice to decide himself in favour of such a product or not. Such labelling should also be applied for additives, flavouring substances or extraction solvents which for the time being are exempted from the Novel Food Regulation.

12. Concerning labelling of foodstuffs produced from genetically modified soybeans and maize Austria congratulates the UK-Presidency for having put forward a compromise text which was adopted by the Council (Agriculture) on 25 May 1998 and which seems also to be a good basis for labelling further novel food products being marketed according to Regulation 258/1997.

As mentioned above this labelling should in any case also comprise labelling of additives, flavouring substances and extraction solvents.

THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF INDUSTRY AND ON COMPETITION

13. The Austrian Genetechnology Act, which came into force in 1995, is a clear and comprehensive legal basis for every industry and research. Nevertheless genetechnology has been the subject of highly controversial public discussions in Austria in particular concerning its applications in agriculture and in food production.

14. Public acceptance of these applications in Austria has slumped down to a very low level.

15. In particular last year the Austrian Parliament had to deal with three major postulations of the Austrian Public Initiative against genetechnology (no production of genetically modified foodstuffs, no deliberate releases of GMOs in agriculture and no patenting of life).

16. As general prohibitions are not compatible with European law the Austrian Parliament has strived to regain some confidence of the Consumer in genetechonology by passing an important amendment to the Austrian law on genetechonology on 16 April 1998.

This amendment contains the following major new elements:

17. New procedural rights for the participation of neighbours, involved communities and provinces in the administrative procedure for a permit for deliberate releases of genetically modified plants;

18. higher transparency concerning information of the population on all documentations in connection with the application for such a permit;

19. nomination of additional experts in the field of ecology and five related sciences to the scientific committees established to assess the applications and their consequences for health and environment;

20. higher penalties for illegal deliberate releases;

21. establishment of new rules for liability (strict liability without a prove of fault) concerning damages to health and environment caused by experiments with GMOs or by the deliberate release of GMOs.

22. We think that in particular this new law on liability for such damages might be an important step in the endeavours of Austria and the European Union to arrive finally at a harmonized general regulation of liability for damages on the environment.

23. Concerning the effects of a strict regulation like the Austrian Act on Genetechonology on the different sectors of industry and competition Austria holds the opinion that strict but applicable and transparent rules on genetic engineering activities are also in line with the interests of industry and research in connection with adequate information and education of the public by all stakeholders involved.

5 June 1998

Memorandum by British Society of Plant Breeders Limited

1. BSPB Ltd represents the interests of plant breeders covering all farm crops (except sugar beet), vegetables and some ornamentals. The society's principal vote is to licence and collect plant variety royalties. In 1996-97 the society collected and disbursed £24.7 million royalty income.

2. Biotechnology plays a vital role in many of the society's members research programmes. It is an enabling technology that facilitates the breeding of new crop varieties which enhanced value to agriculture. Such improvements include resistance to pests and diseases, and increased yields and better nutritional characteristics.

3. Biotechnology will allow plant breeders to continue to have a beneficial impact on agriculture, horticulture and the environment. The technology has value for developed agricultural systems like Europe and the UK (and North America) as well as potential to help the development of sustainable agricultural systems in other parts of the world. The long term export potential for British breeders will be enormous.

4. The first products developed from the use of this technology are based on changes controlled by single gene traits (herbicide tolerance, insect resistance). In time more complex gene combinations will be obtainable with even higher added value for the plant breeding industry and UK agriculture.

5. The committee should be aware of the UK's influential role in developing and implementing regulations covering this technology. The regulations are science based, have been carefully considered and sensibly introduced. The UK example has been used as a template by other countries outside Europe. In contrast, the European system has not been successful being prone to indecision and political interference with little leadership apparent.

6. Regulatory uncertainty is a significant problem in plant breeding because of the lengthy timescales involved in producing novel varieties. This uncertainty leads to a negative climate, notably on consumer perceptions of the new technology.

7. In addition the European regulations have not kept pace with the technology. As an example the European Novel Food Regulation became law in 1997 after almost a decade of debate. There are still no EU labelling guidelines for genetically modified food.

8. The lack of leadership by the EU leads to increased costs and delays in variety development. In the decision making process in developing new varieties the cost of regulatory approval and the schedule for achieving this status are key factors. At the moment it is not possible to estimate these factors of cost and timing. A good example is the gm tomato paste which has yet to be approved in the EU despite UK approval in January 1995. There is still no regulatory approval to grow and process these gm tomatoes in the EU. This position is in stark contrast to North America where approvals take around six months.

9. These uncertainties feedback into the industries involved. These adversely affect SMEs with the net effect that the European entrepreneurial position is weaker than in North America. This in turn discourages investment.

10. This climate of confusion undermines public confidence in the technology which leads to a feedback effect on the regulators which again produces a downward spiral. Without clear leadership the position will get worse with potentially damaging consequences for UK plant breeders.

11. International trade in gm plants and seeds will be affected, with trade disputes the likely consequence of inadequate harmonisation of the regulatory process.

12. The science base of the regulations must not be compromised. The principles of risk assessment are sound and our politicians and leaders must respect the independent advice given by our scientific community. The risk assessment approach should not be expected to give political, sociological or ethical decisions an undeserved credibility.

13. The only valid approach to a risk assessment on biotechnology in plant breeding for agriculture is based on a case by case approach. Each crop species and novel trait should be examined independently. It is misleading to decision makers and consumers to be told that the risks posed by different crop plants are the same—it is equally unhelpful to assert that all applications are dangerous or safe!

14. The overall effect of this lack of clarity and unpredictable planning will have serious long term effects on Europe's competitive position.

5 June 1998

Memorandum by the Canadian High Commission

BIOTECHNOLOGY IN CANADA

To date Canada has approved 40 crops derived from biotechnology. These crops include canola, tomatoes, potato, corn, soybean, flax and cottonseed oil.

This information is summarised on both the Canadian Food inspection Agency's Internet site at <http://www.cfia-acia.agr.ca/english/food/biotech/bsco.html> and on the Canadian Department of Health's (Health Canada's) Internet site at http://www.hc-sc.gc.ca/dalaphb/datafood/english/main_e.htm.

DEVELOPMENT OF A LABELLING POLICY FOR FOODS DERIVED THROUGH BIOTECHNOLOGY

Three major consultations on the labelling of foods from biotechnology have taken place since 1993. These consultations have included the participation of consumers and consumer groups, environmental groups, companies and industry associations, grocery manufacturers and distributors, farmers, health professionals, etc.

Principles have emerged from these consultations based on stakeholder input. These general principles are listed below:

1. Mandatory labelling of novel foods derived through genetic engineering to identify the presence of:
 - (a) Potential health or safety risks for individuals or population segments.
 - (b) Significant composition or nutrition modifications from the non-genetically engineered food source, for example specific fatty acid profile changes in canola oil.
2. Unless potential health or safety, or significant nutrition or composition changes have occurred, food labels are not required to identify foods derived from genetic engineering.
3. (a) The labelling of novel food ingredients derived through genetic engineering should be understandable, truthful and not misleading.
- (b) Voluntary positive or negative labelling that is intended to indicate that a novel food has, or has not, been produced by genetic engineering is acceptable, on the condition of the above principle, that the claim is factual and not misleading or deceptive.
4. Labelling for religious reasons was viewed as outside the mandate of the government and is being adequately addressed within the framework of religious groups.
5. Canada will consider both domestic and international needs in food labelling matters.

CONSULTATION CONCLUSIONS

1. The results of the consultations are consistent with existing Canadian food laws and with Canadian general food labelling policy for non-genetically engineered foods.
2. These results are being used to determine whether novel foods derived from biotechnology require labelling when they enter the Canadian marketplace. Foods that have undergone a significant change in nutrition or composition will be labelled for that specific modification.
3. As a member of Codex Alimentarius, Canada is committed to working with the Codex Committee on Food Labelling to arrive at a common international position on this matter.

ENVIRONMENTAL IMPACT ASSESSMENTS

1. In Canada, there are consistent regulations for the environmental assessment of agricultural products that are legislated by the following Acts and guidelines: *Seeds Act*, *Feeds Act*, *Fertilizers Act* and *Health of Animals Act*, *Plant Protection Act*. These regulations, together with specific guidelines, detail information requirements and assessment procedures and comprise the Canadian legislative framework for agricultural products of biotechnology.
2. Evaluations are conducted on the basis of the unique characteristics of each product rather than the method of production. All plants with novel traits are assessed for possible impacts on the environment based on the specific modification and the biology of the plant.

20 July 1998

Memorandum by Mr Mark Cantley

Evidence from Mr Mark F Cantley, in a personal capacity, but drawing upon his professional experience,

- (a) as a member of staff of the European Commission, Directorate-General XII (Science, Research and Development) from 1979 to 1992,
 - as a member of the “FAST” programme team (Forecasting and Assessment in Science and Technology), sub-programme “Bio-society”, 1979–1983;
 - as Head of Unit XII-F-1 “CUBE” (Concertation Unit for Biotechnology in Europe), 1984–92, Secretariat of the inter-DG Biotechnology Steering Committee and Biotechnology Regulation Inter-service Committee (“BRIC”), during the preparation of the Directives EEC/90/219 and 220;
- (b) as a member of staff of the OECD (Organisation for Economic Co-operation and Development), 1993–present, heading the Biotechnology Unit in the OECD Directorate for Science, Technology and Industry.

GENERAL OBSERVATIONS

1. As an active participant, on behalf of the European Commission (EC), in the OECD Group of National Experts on Safety in Biotechnology from its beginnings in the early 1980s, I accepted fully the OECD report, published in 1986, *“Recombinant DNA Safety Considerations”*; and its reasoning, reflected in the Recommendation of the Council of the OECD adopted on 16 July 1986 (“concerning safety considerations for applications of recombinant DNA organisms in industry, agriculture and the environment”) which *inter alia* recognised,

“that there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms”.

2. This reflected our experience in DG XII with the operation of the EEC Council Recommendation 82/472 (concerning the registration of recombinant DNA work), the advice of the scientific community (in particular, as articulated by the European Science Foundation, drawing on the recommendations of its Liaison Committee on Recombinant DNA Research), and international experience, particularly in the United States in the years following the Asolomar Conference of February 1975.

3. Nothing that has occurred during the subsequent 12 years has invalidated those judgments, in spite of massive expansion of industrial and agricultural applications of modern biotechnology in many parts of the world and commercialisation of the resulting products. There has nonetheless occurred in Europe, a significant expansion of debate and legislative activity specific to the practice and products of genetic engineering. Similarly under Article 19.3 of the Convention on Biological Diversity (CBD), and a subsequent decision of the Third Conference of the Parties to the CBD, considerable effort is currently being devoted to the drafting of a proposed “Biosafety Protocol”.

4. The reasons for these developments have been political rather than scientific, and details have been recorded in an encyclopaedia article of near two hundred pages.¹ The final section, "Synthesis and Conclusions: Learning from History" is attached to this submission, by permission of the publishers (*Appendix*).

A MIS-FORMULATED QUESTION

5. Progress in human understanding, and particularly in science, is often achieved by recognising that a long familiar question is mis-formulated—that it incorporates implicit assumptions which are inaccurate, reflecting ignorance, prejudice or misconception. The OECD statement quoted above did not dismiss the many and various risks to human health or the environment which could arise in handling pathogens, importing exotic species, or running large-scale industrial fermentation plants. But it sought to emphasise that risks typically arise, not from the use of specific molecular techniques of great precision *per se*, but from the nature of the organism being handled, the gene(s) being introduced, and the context of the application. And many of these risks are long familiar, and have given rise to appropriate risk management procedures, implemented by various prudent practices, the training of professionals in the matters concerned, and corresponding regulatory and enforcement systems.

6. This recognition led subsequent OECD work on safety in modern biotechnology to fragment into more specific consideration of the various different sectors of application—in live vaccines, as biofertilisers, in foods, in agricultural crop plants, etc. We would not wish to dismiss as valueless the intensive scrutiny which has been brought to bear upon biotechnology-derived innovations and applications, in agriculture, the food chain, vaccinology and other fields. Various agricultural practices have been highly destructive of the environment, and even inappropriately directed scrutiny can have accidental benefits in contributing to more prudent practices. But although burning down the house to produce roast pig sometimes works, it is not a rational or efficient method.

SECTORAL OR HORIZONTAL?

7. The above reasoning was generally accepted in the European Commission and at Council in April 1990, when the Directives 90/219 and 220 were adopted. The Commission had felt itself obliged to legislate on the technology, in spite of OECD advice and US example, because it was faced with a proliferation of divergent national legislation, starting with the Danish Gene Technology Law of June 1986. The Catenhusen Commission (on Opportunities and Risks of Gene Technology) reported in January 1987, advocating legislation in Germany, which followed in 1990. (In both cases, the adverse consequences and absence of benefit from this restrictive legislation forced subsequent major amendment).

8. It was also clear that the advent of gene technology presented a major opportunity to expand the authority of Environment Ministries, who encouraged and welcomed the initiative which was prepared within the Commission by the corresponding Directorate-General, DG XI (Environment).

9. However, in deference to scientific opinion and the demands of existing regulatory authorities, the Commission's proposal acknowledged the logic of returning regulatory competence to the sectoral authorities concerned, even for the products of novel technology. It was clearly understood (and recorded by a Commission declaration in the Council minutes of 23 April 1990²) that, as modern biotechnology moved into application in various sectors, the sectoral legislation would add as necessary environmental safety requirements; and oversight of the placing on the market of genetically modified products would revert from Part C of 90/220 to the sectoral legislation concerned (cf Paragraph 2(b) of Article 10). An obvious example is in the Novel Foods Regulation.

10. In practice, there has accumulated a substantial institutional investment, and stigmatisation of GMO products, which in the "post-BSE" climate of generalised distrust of innovation in the food supply makes it politically difficult to relax the current irrational and excessive regulation of such products. This apparently prudent behaviour in fact endangers human health and the environment, in diverting always limited administrative and scientific resources from real problems (e.g., the rise of food poisoning, AIDS, BSE³) to pseudo-problems. It is the more unfortunate, in discouraging investment in the use of these inherently safer and

¹ "The Regulation of Modern Biotechnology: A Historical and European Perspective. A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the 20th Century", Mark F Cantley. Chapter 18 (pp. 503-681) of Volume 12: Legal, Economic and Ethical Dimensions (edited by D Brauer), of the Multi-Volume Comprehensive Treatise Biotechnology (Second, completely revised edition), edited by H-J Rehm and G Reed in co-operation with A Puhler and P Stadler. Pub: VCH, Weinheim, 1995.

² Commission Declaration, in the minutes of the Council Meeting, 23 April 1990: Re Art. 10(2) of 90/220/EEC: "The Commission undertakes, when preparing legislation on marketing authorisation for products consisting of, containing or which could contain GMOs, to include in its proposals provisions for a specific environmental risk assessment of the product similar to that provided in this Directive. The Commission also undertakes, where appropriate, to propose modifications to existing product legislation in order to provide for such environmental risk assessment."

³ At a time (around 1990-91) when the Commission was liberally encouraged and enabled to finance research projects on "safety of GMOs", concerned staff had grant difficulty in mobilising resources for a Europe-wide research effort on spongiform encephalopathies—the risks of which were highlighted in the OECD's report (then in preparation), "Biotechnology, Agriculture and Food" (1992)—see p. 66.

more precise tools, e.g., for less dangerous and more efficacious vaccines, for better control of microbial pathogens in food production, and for more environmentally friendly means of plant protection in agriculture.

11. It may be appropriate to recall the plea of that great scientist and writer, Rachel Carson, in *Silent Spring* (1963), for more rational approaches to the control of pests:

"We stand now where two roads diverge. But unlike the roads in Robert Frost's familiar poem, they are not equally fair. The road we have long been travelling is deceptively easy, a smooth superhighway on which we progress with great speed, but at its end lies disaster. The other fork of the road—the one "less travelled by"—offers our last, our only chance to reach a destination that assures the preservation of our earth.

A truly extraordinary variety of alternatives to the chemical control of insects is available. Some are already in use and have achieved brilliant success. Others are still in the stage of laboratory testing. Still others are little more than ideas in the minds of imaginative scientists, waiting for the opportunity to put them to the test. All have this in common: they are *biological* solutions, based on understanding of the living organisms they seek to control, and of the whole fabric of life to which these organisms belong. Specialists representing various areas of the vast field of biology are contributing—entomologists, pathologists, geneticists, physiologists, biochemists, ecologists—all pouring their knowledge and their creative inspirations into the formation of a new science of biotic controls."

That seems a far-sighted and prescient description of what modern biotechnology, through its inter-disciplinary efforts, is currently delivering through the seed industry.

APPROPRIATENESS

12. From what is said above, it should be clear that I view current regulatory structures for biotechnology in the EC as inappropriate, ill-conceived, and dangerous to the purposes they were thought to serve. In support of this, I would quote (as one authoritative example among many) the Director-General of the International Food Policy Research Institute, Dr. Per Pinstrup-Andersen, speaking at an OECD "Forum for the Future" conference held at OECD in June 1997, on "Agriculture on the Threshold of the 21st Century":

"There are indications, however, that public pressure in Western Europe is likely to move governments to introduce legislation that will constrain or prohibit full utilisation of the opportunities offered by genetic engineering and other tools of modern science to be applied to food production and processing. Should such legislation spread within Western Europe and to the rest of the world, including the developing countries, the consequences for food security and nutrition could be severe . . .

Unfortunately, there is also a trend in several European societies to begin to consider that the application of science to agriculture may be part of the problem rather than part of the solution. Failure to understand that productivity increases in food production are an essential component of a future with food security for all has moved powerful societal groups to push for severely constraining legislation on agriculture research."¹

THE FOUR ISSUES

13. Based on the above general background, history, and the supporting materials cited, I would offer the following summary responses to the issues particularly mentioned in the request for evidence:

1. *The appropriateness and efficacy of current regulation of*

- (a) research,
- (b) release into the environment and
- (c) novel foods and their labelling

at European Union level

Response: largely inappropriate, inefficient and counter-productive, endangering health and the environment, and delaying beneficial innovations. The accompanying propaganda efforts by certain non-governmental organisations in Europe, with a talent for media publicity, have contributed to substantial misinformation at all levels, from the general public/consumers, to political leaders.

¹ "Major Uncertainties and Risks affecting long-term Food Supply and Demand", by Per Pinstrup-Andersen and Rajul Pandya-Lorch, IFPRI, paper presented at the OECD Forum for the Future, "The Agro-Food Sector on the Threshold of the 21st Century", Paris, 24-25 June 1997.

2. *The appropriateness of current regulation at the level of the United Kingdom and other Member States*

Response: As Part B of Directive 90/220, relating to the control of research, is subject to national regulation, the UK has the opportunity (which it uses) to apply a balanced and pragmatic approach via bodies such as HSE and ACRE; but for commercial releases, the UK like other EU Member countries is constrained by the EU-level requirements and procedures of 90/220.

3. *The most appropriate jurisdictions, (including international regulation and harmonisation) for decisions on genetically modified organisms*

Response: as was remarked by Montesquieu (*De L'Esprit des Lois*), "if it is not necessary to make a law, it is necessary not to make a law". There is no need for any "GMO-specific" jurisdiction, national or other. For those sectors some of whose products may require international regulation, and in which current or future products may comprise or contain GMOs, the most efficient and competent jurisdictions or bodies are likely to be those currently in place—e.g., the International Office for Epizootics, the OECD Seeds Schemes, the World Health Organisation, etc., for the various product groups falling within their areas of expertise and formal competence.

4. *The effect of regulation on different sectors of the industry and on competition*

Response: the effects have been, and increasingly continue to be, massively detrimental to Europe as a location for research, development and commercialisation of products of modern biotechnology. The impact on the location of research and production facilities (i.e., to drive them outside Europe or dissuade inward investment from elsewhere) is already clear in the context of the pharmaceutical industry, the seed industry, and modern animal biotechnology.

4 June 1998

APPENDIX

1. Final section of "*The Regulation of Modern Biotechnology: A Historical and European Perspective. A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century*"; Mark F Cantley. Chapter 18 (pp 505–681) of Volume 12: Legal, Economic and Ethical Dimensions (edited by D Brauer), of the Multi-Volume Comprehensive Treatise Biotechnology (Second, completely revised edition), edited by H J Rehm and G Reed in co-operation with A Puhler and P Stadler. Pub: VCH, Weinheim, 1995. For references cited, see the original, full text.

8. SYNTHESIS AND CONCLUSIONS: LESSONS FROM HISTORY

2. In 1981, the Nobel prize-winning American, James Watson, and the Secretary of the European Molecular Biology Organisation, John Tooze, published "*The DNA Story: A Documentary History of Gene Cloning*". With their narrative, they interspersed the principal documents associated with the pre- and post-Asolomar discussions, from 1973 through to the end of the 1970s, documents which illustrate the rise of the once-threatening tide of Congressional legislation, and of the widespread public concern and criticism which drove it. A few of the same elements are briefly reviewed in the first Chapter of this review; the Watson and Tooze compendium fills over six hundred pages. In the closing paragraph of their final section, "Epilogue", the authors conclude with evident relief:

"Politics and politicking preoccupied the first years of the recombinant DNA story, but that phase, fortunately, is fast becoming history. This book is our epitaph to that extraordinary episode in the story of modern biology".

3. More than a decade later, no such facile conclusion can be offered in a history of biotechnology regulation; one thinks rather of a contemporary historian in Europe's Thirty Years' War, or in the Anglo-French 100-year conflict, invited at year 10 or year 20 to give an overview and prediction of outcomes . . .

4. For the "politicking", although it paused in the early 1980s, picked up momentum thereafter and has increased ever since, *pari passu* with the progress of the science and the diffusion of biotechnology. In Europe, the politicking was more intense, and the initial outcome less happy than in the US; for the surge of knowledge and innovations coincided with two other historic processes. The mid-80s saw a surge of political support for environmental movements, which in parts of Europe tapped into older romantic traditions, containing strong anti-intellectual and anti-technological elements. Lönngren (1992) speaks of "the politicisation of chemicals control". At the same time, the political will and leadership in Europe, at both Community and national levels,

was ready to drive forward the processes of constitutional change and development. The potential for such development had always been present in the founding EC Treaty, but the drive was accelerated from the mid-1980s by an impatience with slow progress, and by a will to “build Europe”. These were given concrete expression by the 1992 target date for completing the common internal market, and by the Single European Act (adopted 1987, effective 1989) as the instrument for its completion. Majority voting for proposals under Article 100A (the legal basis for harmonising legislation), and for specific R and D programmes within a (still unanimity-requiring) multi-year Framework Programme, were among the several significant innovations of this Act.

5. The momentum was maintained, through the three successive Commissions during the ten-year presidency of Jacques Delors—at least to its penultimate year, 1993, which saw the ratification of the Treaty on European Union, signed at Maastricht in December 1992. By 1993, however, it was “a damn close-run thing” (as Wellington remarked at an earlier defining moment in European history), with a second plebiscite required in Denmark, a wafer-thin assent even in France, and the ruling British Conservative party almost mortally split. The continued decline in numbers voting in European Parliamentary elections (in June 1994), and the divisive political arguments accompanying the 1994 plebiscites in Austria, Finland, Sweden and Norway, on accession to the European Union, underlined the slackening of political will.

6. This political backdrop interacted repeatedly, and often unnecessarily and unhelpfully, with the development of biotechnology in Europe. The politicking hindered, where it should have facilitated, the effective integration of the new knowledge into the activities and sectors that needed it. Conversely, the history of Community strategy for biotechnology in Europe, and the history of biotechnology regulation to which for some years it seemed to be reduced, illuminated structural weaknesses within the Commission, and within the Community’s institutional structure. These structures were ill-adapted to managing the challenges and complexities of biotechnology; for even when these were clearly identified and described, in good time, the communication to the political level was generally ineffectual; and political action was blocked or diverted into irrelevant and unhelpful actions by the weight of other interests.

7. Many factors render obscure the legislative and other actions of the Community institutions, shielding them from effective democratic scrutiny, and limiting their transparency: the multi-institutional complexity (Commission, Parliament, Council, etc.) of the machinery; the distance from national politics (where “Brussels bureaucracy” is a convenient scapegoat for nationally unpopular measures), and from citizens and local communities; and the inescapable diversity of Europe’s languages and cultures, at once its glory and a permanent political constraint.

8. This lack of transparency means that on complex subjects, only a sustained and determined effort of communication can ensure that all parties with relevant interests and knowledge have the opportunity to participate in preparing proposals and decisions; and when the mass of information and opinions is effectively elicited, there has to be a radical condensation and filtering to summarise the debate into the drafting or amending of a legislative text, or to enable the elected parliamentarian to cast his vote. Both in the communication, and in the condensation, the opportunities for distortion, accidental or wilful, are legion.

9. Complexity without transparency allows, even encourages, the pursuit of individual and institutional self-interest. Key individuals involved in the biotechnology regulatory agenda differed widely in their interests, their style of operation, and their attitudes to science, innovation and industry.

10. Within the Commission, each Directorate-General has its “déformation professionnelle”, and the linguistic barriers are trivial in comparison to those between DGs. The Commission as a whole is by constitution naturally activist, and that constitution reflects the political aims of the founding Treaties: there was much to be done. This maps down to the level of the individual, particularly in the Directorates-General concerned with legislation: success tends to be equated with the adoption of a new Directive or Regulation, however flawed.

11. Thus in DG III, legislation was essential to creating a common market—for food products, pharmaceuticals, etc., and ultimately to achieve new structures such as the European Medicines Evaluation Agency. Similarly for DG XI, the control of chemical products for the protection of human health and the environment, was a major challenge, the legislation a major achievement, and the basic need for such control—whatever the disputes about details—essentially an unquestionable imperative, world-wide. DG V’s responsibilities for promoting uniform high standards of worker safety similarly demanded and brought forth a constructive and successful framework of Community law.

12. The Commission embraces other aims and their corresponding cultures. The Common Agricultural Policy was the creation of the Community institutions, its management and defence the burden of DG VI; who had simultaneously to respond to world-wide pressures for change—for the liberalisation of agricultural trade under GATT, for protecting rural interests under the pain of “rationalisation”, and for reconciling the diverse European interests represented by the Ministers of Agriculture. Biotechnology, uninvited, came insistently onto the DG VI agenda via agricultural research and agricultural legislation, offering productivity increases in sectors plagued by excess production.

13. The culture of DG XII, especially in its earlier decades, was scientific in its sympathies and roots. They were reluctant legislators in 1978, glad to retire from such matters in the mid-80s. Global trends—the move towards knowledge-based economics, the natural internationalism of science, its perceived relevance to economic competitiveness, the increasingly expensive and specialised character of research—led to rapidly expanding biotechnology R&D programmes at European level in the late 1980s and 1990s. The pressures of managing these increasing resources with a static or declining complement of staff forced DG XII to focus on the politics of winning these heavier research budgets, and on managing efficiently the selection and administration of vast numbers of projects. These pressures further diminished the appetite for inter-DG arguments over legislation; but paradoxically increased the need for such interaction, as the expending R and D activities, and the global trend to more knowledge-based economies, were inexorably increasing the scientific content in the agenda of other DGs. DG XIII—responsible for the large R and D programmes in information technology and telecommunications—was from the mid-80s closely involved in the full range of research, industrial policy, and related legislative activities. For biotechnology obtruded across the range of DG interests, and no single DG could pretend to a monopoly of scientific wisdom, even within the life sciences and technologies.

14. The first FAST programme, and the Commission's 1983–84 responses, establishing the Biotechnology Steering Committee, reflected an adequate perception and analysis of the challenges, followed by apparently appropriate action. The "need for an integrated approach" was similarly endorsed by Parliament, in the 1987 Viehoff report and the resolution adopted.

15. The subsequent fading of the Biotechnology Steering Committee has been described. As the new techniques of genetic engineering were emerging from the laboratory to cross the road to the market-place, the bus of environmentalism was accelerating; and although the new techniques could fairly claim a place on the bus, as "Clean Technologies", the interaction in Europe was more a collision than an accommodation or a welcome.

16. The self-confidence of success led to an uncritical and inappropriate transfer of the culture of chemicals control to legislation focussed on, and by inescapable implication stigmatising, a technology. Many factors reinforced this strategic blunder: widespread scientific illiteracy, sensationalism in the media, bureaucratic and political opportunism, agricultural protectionism, mistrust of industry, an anti-industrial, anti-intellectual populism—and the usual scientific uncertainties and caution.

17. Oversight in the form of notification and monitoring is a rational response to uncertainty, and enables uncertainties to be diminished by the accumulation of experience, and resources for risk assessment and management to be rationally deployed. This was the approach adopted by the Community in the 1982 Council Recommendation; and it worked satisfactorily, not least because there was no attempt by DG XII, the service *chef-de-file*, to exploit the opportunity to build up a permanent bureaucracy.

18. In the United States, the effective dialogue between scientific and political communities headed off the threat of technology-specific legislation, and even those who (unsuccessfully) advocated and prepared such legislation in the 1970s and 1980s, typically incorporated in their Bills a "sunset clause", which would automatically terminate the legislation after a set period, if there was no further Congressional action taken to renew or amend it.

19. Such a "provisional" or "learning" approach was a rational and scientific response to uncertainties about a new phenomenon, such as a new technology. But for new chemical substances, or pharmaceutical products, there is the practical certainty of a continuing stream of new entities requiring testing and oversight; and the corresponding administrative structures are therefore conceived on permanent lines, give or take some future adaptation.

20. The imposition of this "permanent" character on novel technologies both stigmatised them, and built a bureaucratic structure at Community and national levels with an in-built tendency to justify and defend its continued existence.

21. Within the European Parliament, the active members, coping with a flood of documentation, and a complex and exhausting life-style (between home, committee work in Brussels, and plenary sessions in Strasbourg), could in general devote little time to understanding complex dossiers such as biotechnology.

22. While there could be real concerns about ethical aspects of the use and abuse of new technologies (e.g., in relation to human genetics or animal welfare), and popular suspicions of "mad scientists" and mistrust of industry, in general the esoteric character of genetic engineering meant that practically all MEPs would leave such a dossier to the rapporteur—or, if the rapporteur was not of their political group, would designate a member of their group to follow the dossier. The basis for formulating the parliamentary opinion on legislation relating to biotechnology was therefore typically a very narrow one; in an area which shared (with nuclear energy) the most concentrated attention of the "Green" fraction in the Parliament. Moreover, even MEPs not of this fraction, were in many countries acutely conscious in the late 1980s that the major political parties were losing ground to the Green movements; and to recapture these votes, were anxious to demonstrate their own "Green" credentials. A severely restrictive approach to the highly publicised new gene technology appeared to be a painless and popular way of doing so.

23. Against this coincidence of popular fears, political self-interest and bureaucratic opportunism, the voices of scientific protest were few, feeble and disregarded. DG XII lost the arguments inside the Commission, and had at the critical moments no interested allies. The protests to Parliament by Nobel prize-winners did not represent a politically significant constituency. The OECD report on rDNA safety, indicating no scientific basis for legislation specific to recombinant DNA, was quoted for its prestige and authority, in support of precisely such legislation. The advice of the safety specialists of the European Federation of Biotechnology was aggressively rejected by the Director-General of DG XI. The House of Lords Committee's report noted that in drafting the legislation, the Commission had been "impervious to scientific advice"; in fact the efforts of DG XII to offer such advice, as they were (by the Council Decisions on BAP and BRIDGE programmes) required to do, were vigorously repulsed and successfully counter-attacked.

24. A similar "knee-jerk" reaction greeted the suggestion (in the Biotechnology Regulation Inter-service Committee, around 1987) that the details of a fast-changing and complex field might best be addressed by technical experts in standards committees. DG XI was Chef-de-File for biotechnology legislation, but not for standards. As a result, technical details of scope—a central issue in the US debates—were defined in Annex I of each "biotechnology" Directive, 90/219 (contained use), and 90/220 (field release), in terms specific to the legislators' understanding of the science of the 1980s, as modified by the experts chosen by the Environment Ministers, who then removed these defining Annexes from the scope of the committee procedure for adaptation to technical progress. The consequences in costs, delays and controversies would dominate the regulatory debate throughout the 1990s.

25. The silencing of Galileo no doubt seemed to contemporaries a matter of limited significance, beyond the scientific and theological communities; but by 1990, biotechnology was beginning to matter, and countervailing forces were coming into play, to correct the strategic error. Industry in Europe, following the widely publicised meeting with Davignon of December 1984, had established a communication network for the expression of bio-industrial interests, but failed to endow this with muscle. By continuing to devote their main energies to sectoral channels, they confirmed a similar conservatism within the Commission.

26. The change of perspective from 1989 was attributable to the significance accorded to biotechnology in less constrained environments (such as the USA), or in those where long-term strategic vision was taken seriously (as in Japan). Multi-national companies operating in several continents could most readily compare the differences of approach, and their implications for regulation. Although they could to some extent re-locate their activities and investments to adapt to circumstances, this had costs and discomforts, particularly for those whose base operations and major investments were in Europe; and for all firms, wherever based, the European market was a major element of the global total.

27. The loss of investment (actual and threatened), and the loss of R and D activities and personnel, the seed corn for future industries, inevitably attracted political concern, particularly once linked with the rising political concerns about employment. The constitution of the SAGB at European level, the various national bio-industry associations, and the US examples, ensured an attentive hearing for industry once it started to express itself vigorously at political level, from 1990 onwards; but their intervention was late, and did not have enough momentum to divert the legislative juggernaut in that year.

28. Within the European Commission, the consequences of the failure of inter-service co-ordination were gradually recognised at the highest level; and in 1990 the Secretary-General at the request of President Delors initiated the Biotechnology Co-ordination Committee. More importantly, he maintained and developed the central role of the BCC within the Commission services; thus acting as a brake on the autonomous behaviour of individual DGs, and enforcing a greater degree of horizontal transparency within the house. Also during the early 1990s, the Commission was responding to the need and political demands for greater external transparency (European Commission, 1993); and within the BCC framework, "Round Tables" with industry and with a wide range of non-governmental interests became a regular feature of its activities. The 1991 communication similarly announced that CEN (the European Standards Committee) would be charged with a mandate to develop standards in biotechnology.

These developments were neither trivial nor obvious: the suspicions and hostility vis-à-vis biotechnology which had driven, and been reinforced by, the 1990 legislation were far from dissipated. If a Directorate-General was disgruntled at BCC, a "phone call or a fax could quickly trigger a forceful letter from a sympathetic MEP to the Secretary-General, and there would not be lacking groups and activist organisations to carry the argument to the public domain, *mutatis mutandis*—and the mutations could be remarkable.

30. Moreover, the "public domain" for argument was dramatically enlarged as the UN agencies progressively recognised the need or opportunity for each of them to engage with biotechnology. Particularly damaging were the renewed and amplified opportunities for stigmatisation offered by Article 19.3 of the Convention Biological Diversity, with its invitation to consider the need for an international "bio-safety" protocol. Using these international fora to reinforce one's local position was an instinct as natural to the conflicts in Brussels as in Bosnia.

31. The prominence of biotechnology regulatory matters in the Commission's December 1993 White Paper on "Growth, Competitiveness and Employment" has been noted in the previous section, along with the follow-up action in the communication at the Corfu Summit, and in the regulatory proposals submitted during the German and French Council presidencies of 1994–95.

32. These developments clearly display the capacity of the European Commission, of industry, and of national political leaders to be responsive, and to limit and reverse the past mistakes. But as Heraclitus observed, one cannot step twice in the same river. The waters of public opinion have been muddied by misrepresentation, and there remains enough continuing uncertainty and concern to slow the work of reorienting policies and of adapting or dismantling the legal and administrative structures whose foundations are now questioned.

33. The European Parliament has yet to re-address the central issues of biotechnology regulation. As the renewed European Parliament (after the June 1994 election) struggles for increased power in the Union's inter-institutional debate of the mid-1990s, it is difficult for it to acknowledge that it goofed in earlier years. Institutional face-saving is no less endemic in the national Ministries concerned, and within the Directorates-General of the Commission. However, bureaucratic drafting skills, changes of government, and internal reorganisation are all instruments through which such changes can be respectably managed, and all will have their role.

34. Parliamentary debates—and votes—on specific challenges such as the Directive on the Protection of Biotechnological Inventions, or the Novel Foods Regulation, continue to give cause for concern to those focusing on Europe's economic competitiveness. Biotechnology is not yet recognised as integral to the future competitiveness of agriculture and of major sectors of industry, as well as to the effective improvement of public health and the protection of the environment. Ethical issues, such as those highlighted in the Council of Europe's draft Convention on Bioethics (1994), will continue to attract greater prominence in Europe; with the risk of consequent relative neglect and damage to the bases of Europe's economic (and consequent political) weight in the 21st century.

35. To paraphrase the Watson and Tooze "Epilogue" quoted at the start of this section: politics and politicking preoccupied the first years of the recombinant DNA story, and that phrase, in Europe and more than a decade later, became, unfortunately, not "history", but a story of arrested development. The internal conflicts within the Commission are for the moment better controlled, but much energy in Brussels is still devoted to inter-institutional and Community-national conflicts, on constitutional matters which the USA settled 13 decades ago; and to the geographical expansion of the Community.

36. Insofar as wider international relations and activities come into play—for example, through EC-US bilateral, OECD, or UN agencies—the tendency is for the contending interests, within the Community institutions and at national level, to use such wider dimensions to reinforce their position in domestic conflicts,

37. As Europe's political leaders and public servants battle for control on the bridge of their Ship of State, and prepare for the Inter-Governmental Conference of 1996–97, they must remember there's ocean out there (and rocks)—not just more and more ship. On the swelling and stormy oceans of knowledge, not least, of the life sciences and technologies, forecasting and navigational skills, and institutional and political structures capable of using them intelligently, will be more than ever essential.

Memorandum by Consumers in Europe Group

INTRODUCTION

1. Growth in the biotechnology sector of the food industry in recent years has been enormous and is likely to accelerate in the future. New technologies, new raw materials and the use of genetic engineering in the food sector have resulted in the rapid development of novel foods, ingredients and processes. An increasing proportion of the food we eat is likely to come from genetically modified organisms (GMOs) and their derivatives. Such developments could potentially lead to significant changes in the composition of individual foods and subsequently to overall nutritional and toxicological effects on an individual's diet. It is therefore of the utmost importance that a sound legislative framework for evaluation and approval of new substances and foods operates within the EU to guarantee to consumers that all necessary steps are being taken to ensure the safety of genetically modified food.

2. CEG is not against biotechnology in itself provided it is closely controlled. Preventing progress in developing genetically modified (GM) foods is not in the consumer interest: however, the emphasis must be on caution, maximum information and learning from the past. It must be recognised that some customers, for a range of reasons, may choose to avoid eating GM foods and they must be able to express that choice.

3. The consumer interest must be represented in the approval process to ensure the *safety* of new products and processes, to maintain and open up *choice*, to create *access to information* on the novel foods and processes used to produce them, and to *protect* the environment.

APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION OF RELEASE INTO THE ENVIRONMENT

4. CEG welcomes the steps taken to clarify the approval procedures within the Commission's proposed revisions to the current directive on release into the environment (90/220/EEC). We acknowledge that the approvals process could be simplified but this should not mean that the protection of human health comes second

to commercial interests. The pursuit of speed and reduction of documentation should not reduce the opportunities available for consumers to give their views.

5. There needs to be a link between all EU legislation on GM products to ensure consistency of approach, especially between the Novel Foods Regulation and Directive 90/220/EEC. This coherence in policy was implied in the Commission's 1997 orientation on labelling.

6. Labelling of GM produce is a key area of concern and, as such, needs to be covered in more depth than is currently proposed in amending Directive 90/220/EEC. All seeds and agricultural produce from GM plants must be labelled; animal feed containing GM material must also be labelled. CEG does not support the use of "may contain" labelling because it does not give any helpful information to consumers. Moreover, the information and labelling of GMOs and GM produce must enable them to be traced back through the food supply. This would give the opportunity to recall products should any adverse health effects occur.

7. Further clarification is needed on the important aspects of how the assessment of risk to health and to the environment will be carried out. There needs to be a clear methodology developed for risk assessment. Assessments must be standardised throughout the EU. Where the scientific information needed for a risk assessment is insufficient or inconclusive then this should be made clear and any decisions based on that assessment should err on the side of safety to the public.

8. Consumers are concerned that there may be adverse long-term effects from the cultivation and use of GMOs. These effects may not be apparent at the time of approval because of their long-term nature. It is crucial that the approval process requires that the impact on human health and on the environment is monitored, and reported back to the regulatory authorities. The impact of both individual products and also of genetically modified products as a whole need to be considered. Guidelines are needed on the methodology to be used for monitoring, for the treatment of waste and for emergency response. The frequency of monitoring and the techniques to be used should be specified. In addition, farmers may need training to recognise potential problems caused by horizontal gene transfer from GM crops to other crops or weeds.

9. The approval process must be open and transparent. The dossiers provided by companies for approval of releases must be made available to interested parties. We consider that it is particularly important for competent authorities to be provided with the full dossier on request. They must be able to fully assess the data in order to make any appropriate substantial objections to the release and/or marketing of a GMO.

APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION OF NOVEL FOODS AND THEIR LABELLING AT EU LEVEL

Approval process

10. An effective approval process based on sound scientific evaluation is of key importance for ensuring the safety of novel foods and processes. These are essential for the consistent assessment of applications by Member States. The Scientific Committee for Food (SCF) should be closely involved in the approval procedures for novel foods. The SCF should be consulted, and provided with a copy of the initial assessment report, whenever an assessment for authorisation is referred to the Standing Committee for Foodstuffs and there are concerns for human health. The Scientific Committee for Food's guidelines for applications should be reviewed and updated once the new procedures have been in operation for a couple of years.

11. All novel foods must undergo an appropriate safety assessment by an officially-designated competent authority. It should not be acceptable for companies to place novel foods directly onto the market based only on their own evaluation of substantial equivalence; however, this is allowed under the EU Novel Foods Regulation. This loophole for establishing the substantial equivalence of novel foods should be closed as soon as possible. Until then, the UK's Advisory Committee on Novel Foods and Processes (ACNFP) should evaluate, as a matter of priority, all the supporting evidence for substantial equivalence provided by companies to the Commission and take immediate action if there are concerns for human health.

12. The approval system must be transparent so that consumers can find out what applications are in the approval system and what procedures are being followed within it. An EU-wide system for monitoring applications for novel foods in the approval process should be put in place by the Commission and regular reports published.

Antibiotic resistance marker genes

13. The presence of antibiotic resistance marker genes in GMOs may create a risk to human health. The concern is that the marker genes could be transferred to a micro-organism pathogenic to humans and so make the control of infection needlessly difficult. This could happen if, for instance, GM maize containing an antibiotic resistance marker gene is used unprocessed (i.e., with live genetic material) in animal feed. The probability that resistance will be transferred is very low but the potential impact on human health could be very great. The precautionary principle should be applied in cases such as this.

14. Antibiotic resistance marker genes are often used in the early stages of the development of GMOs. They serve no purpose after this stage and alternative marker genes are available. It is technically possible to excise the marker gene before the GMO is marketed. To protect public health, GMOs containing viable antibiotic resistance marker genes should not be marketed. The guidelines for scientific assessment of novel foods should make it clear that these marker genes are not acceptable in the final product. Their use in GMO development should be phased out as soon as possible.

Scope

15. The Novel Foods Regulation does not apply to processing aids, additives, flavourings and extraction solvents. However no EU legislation exists on processing aids at present. This means that many enzymes used in the food industry (that are increasingly derived from genetic modification) are not subject to any safety assessment at an EU level. There is also no present requirement to label processing aids. CEG considers that processing aids should be regulated (with priority given to enzymes).

Consumer representation

16. Representation of public interest in the evaluation process is not specifically included in the Novel Foods Regulation. Although some Member States may have some degree of consumer involvement in their own systems, consumers are not represented at the EU level. While the re-organisation of the Consumer Policy and Health Protection Directorate-General (DG XXIV) has led to more open decision-making by the scientific committees, there is scope for more consumer representation. Representation by consumers and public interest groups in the evaluation process of novel foods should be increased.

Areas requiring research

17. Genetic modification is a relatively new technology and there are still many unknowns and uncertainties about its use, especially over the long-term. Research should be directed at some of the assumptions made in the approval process and into methods for detection of GM material in foodstuffs. Research should be funded by the EU and UK into these areas and the effect of processing on the viability of GM material.

Labelling

18. We fully support the principles of consumer choice and information. Therefore, all GM food must be clearly labelled. Consumers must be able to make an informed choice between those foodstuffs produced using genetic modification and those which have been produced conventionally. This is particularly important in the early years of this new technology's introduction. As part of this, non-GM alternatives must be available to consumers to make sure that they have a genuine choice of food products.

19. Segregation of GM produce at source and traceability throughout the food supply chain are the best ways to ensure full and accurate labelling for consumers. CEG considers that the labelling of food from GM crops must be based on derivation, not purely on analysis of chemical differences. This must include processed products from GM crops; many of these would not need to be labelled under EU Regulations. Without credible systems for segregation and labelling, consumers will not know if they are eating GM food, and their confidence in this new technology is likely to be reduced. Segregation systems must be supported by analytical spot-checks at points throughout the food chain to check their validity.

Guidelines

20. The wording of the Novel Foods Regulation is open to interpretation in several key areas including marketing procedures and labelling. Therefore there is a risk that Member States may decide to implement the Regulation in different ways, undermining the Single Market and potentially restricting consumer choice. It would be very helpful to have EU-wide guidelines on the Novel Foods Regulation.

Monitoring long-term effects of consumption

21. Consumers are concerned that there may be adverse long-term effects from the consumption of novel foods. The impact of individual products and also of genetically modified products as a whole need to be considered. Although the Novel Foods Regulation recognises these concerns, more detail is needed on how monitoring will operate.

JURISDICTIONS FOR DECISIONS ON GMOs

22. There is a need for an "over-arching" body, at both UK and EU level, to consider the broad picture of the use of genetic modification and its impact on the environment and food safety. Case by case assessments made under Directive 90/220/EEC or the Novel Foods Regulation do not cover this broader viewpoint. It is

disappointing that the Commission has not set up a Scientific Committee on Biotechnology. The remit of such a committee could extend beyond human health and incorporate environmental and ethical considerations. It could be closely involved in the approval process and be consulted alongside the SCF.

1 June 1998

Memorandum by Co-operative Wholesale Society

REGULATION

1. We are concerned that there are gaps in the statutory arrangements for the authorisation and regulation of genetically modified organisms (GMOs).

UK Regulation

2. In the UK there are several committees concerned with different aspects of the regulatory/authorisation process; the Advisory Committee on Releases into the Environment (ACRE), the Advisory Committee on Novel Foods and Processes (ACNFP) and the Food Advisory Committee (FAC). Each has its own, specific remit. Members are discouraged from discussing issues outside the remit of the particular committee even where such issues fall outside the authorisation process.

3. In particular, the ACNFP and FAC focus exclusively on use for human food. The question of animal feedingstuffs is largely beyond their remit. So, for example, the FAC considers labelling aspects from the viewpoint of use of GMOs directly in human foodstuffs. They do not consider labelling aspects of animal feedingstuffs nor of the human foodstuffs derived from animals fed GMOs.

4. The committees are all wanting in that they consider each GMO in isolation concentrating on a particular product. This does not provide a forum for looking at the overall impact of GMOs. For example, the safety of a particular modification is assessed but no account is taken of similar modifications and the overall impact they might have. For example, there is no official check that would prevent every crop being genetically modified to be resistant to the same pesticide/herbicide. Such a development would be a potentially disastrous scenario in that it would place too much reliance on that particular pesticide. Serious consequences could result from the development of strains resistant to that pesticide. Similarly, if the safety of that pesticide was subsequently brought into question, it would have a devastating effect on food suppliers.

5. Similar criticisms can be applied to European and World-wide regulations.

European Regulation

6. The European regulatory process gives greater cause for concern with its emphasis on compromise rather than judgment of the scientific facts. We are thinking particularly of the judgment with regard to Novartis (Ciba-Geigy) maize containing an antibiotic marker. The UK regulatory process, quite rightly in our opinion, identified a slight risk with this antibiotic marker from which they concluded it was prudent to prevent its inclusion in animal feeds in the raw state. Three European committees debated the issue. Their deliberations were largely inconclusive, yet the UK decision was overturned.

7. The European regulatory process is highly bureaucratic. This may be effective in reaching decisions. It is not necessarily effective in reaching the right decisions. It is also very flexible and therefore inappropriate for a fast moving field such as this where what is right one day may be found inappropriate at a later date. This is especially true in the field of consumer information where we are at one point considering the introduction of a new technology but, in time, it has the potential to be commonplace. Indeed, potentially it could be the non-GMO of which the consumer needs to be informed. We do not have confidence that the European system could accommodate such a shift in opinion/approach.

World-wide Regulation

8. Biotechnological innovation and the development and bringing to the market of GMOs is costly. There is therefore much at stake if a company's application is at risk of being rejected. A country's prestige is also, potentially, at stake particularly where Governments have invested heavily in biotechnology research. These very real pressures also call into question the thoroughness and adequacy of the regulatory process.

9. World-wide the approach of considering each GMO application in isolation and to different criteria is of even greater concern, particularly from the viewpoint of world trade. What is deemed safe/acceptable in one country may not be considered so in another yet there are no mechanisms to contain GMOs within the country in which they are approved. Differences in approaches to labelling make for further complications.

10. This is further exacerbated where GMOs are co-mingled with their regular counterpart. This does appear to be a prime example of something which has slipped through the regulatory net without due consideration of the potential ramifications. Clearly co-mingling of an internationally traded crop by a major producer effectively precludes any other regulatory system reaching a different conclusion on safety, etc. It compromises any labelling commitment. It may, of course, be perfectly justified and any concerns may be esoteric. Something may, in the course of time, emerge which questions the original approval. If this pinpointed a safety risk with the particular GMO it would be impossible to react; to remove it from the marketplace without the removal of all, or all but small amounts of identity-preserved sources of the product in question. This could have catastrophic consequences in the case of a staple food such as wheat.

11. World-wide there are also concerns that conditions of approval linked to an authorisation in one country may not be applied in a second or third country. What is seen as a benefit in developed countries may be assumed to be a panacea for exploitation in third countries where the ability and expertise to instigate such controls is wanting.

12. In addition to wilful exploitation of GMOs throughout the world, the question of uncontrolled expansion should not be forgotten. Crops, and even animals, on their own will not respect borders. There is therefore a feeling of uncertainty as to ultimately how GMOs can be controlled world-wide.

13. These concerns lead us to the belief that there must be international regulation and harmonisation.

LABELLING

14. Labelling goes hand in hand with regulation. As with regulation, there must be international harmonisation. The arguments parallel these detailed above with labelling policies in one country being dictated and/or compromised by different policies in another country.

15. The question of so-called *substantial equivalence* and co-mingling is the fundamental issue in this compromise. As indicated above, where a country permits co-mingling it precludes any other country receiving co-mingled sources from accurate labelling. Indeed, any material which is not labelled at source can not be subsequently labelled with confidence. There must be traceability of GMOs from sowing to final product. This labelling is reduced to the least onerous policy within the chain.

16. At the present time it is not at all clear to what extent products of GMOs should be labelled. There has been an assumption that only materials containing modified DNA and/or protein need to be identified. This philosophy supports a policy of monitoring the impact of such changes on, for example, diet. It does not, however, address the wider concerns of the consumer who wishes to avoid products *downstream* which have an environmental impact *upstream*.

17. Labelling and traceability are essential if there is to be any form of monitoring the long-term consequences.

MONITORING

18. This is a new technology and there has been a recognition of the need to monitor its impact both in the wider sense of its environmental impact but also from the viewpoint of product safety.

19. Safety evaluation is only as good as the tests applied. Long-term consequences of GMO consumption may emerge. The science of insertion of GM material is acknowledged to be imprecise and may, in certain cases, result in a change to a particular food or ingredient which results in an adverse reaction or changed nutritional value adversely affecting expected dietary intakes. It has to be recognised that each, individual, modification of a particular commodity is unique. It is therefore potentially not merely a case of tracking GM soya but of a need to look at each individual GM soya. Such impacts may not be immediately apparent but may emerge only from long-term dietary studies of populations. It is therefore important to monitor the consequences of such long-term exposure.

RESEARCH

20. A major concern with any technological innovation is whether it offers advantages which benefit society or whether it merely pushes back the frontiers of science. There are greater concerns with the introduction of a technology which is not confined to specific, discrete areas but which promises to be all pervasive throughout the animal and human food chain and throughout agriculture. It is therefore worrying that there appears to be no overall co-ordination of research.

21. First and foremost, with the development of such a technology it would have been beneficial to involve recipients (consumers) of the technology before it was forced upon them in an uncontrolled way in the marketplace. It is appreciated that, without real-life examples, it is difficult to involve ordinary consumers.

There are, however, some fundamental issues which could have been elucidated, for example, the question of traceability.

22. As indicated above, there is a lot at stake commercially from the exploitation of GM research. It is important therefore that there is some certainty in the regulatory outcome if a research programme is successful. It is therefore of concern that through this lack of co-ordination later developments in a similar field may be rejected because of concerns of proliferation. We are thinking particularly of the concerns raised with regard to over-use of individual pesticides.

23. We are equally concerned that there seems to be no detailed consideration of the acceptability and overall consequences of research techniques. We are thinking of the use of antibiotic markers, a perfectly acceptable research technique but with long-term and wider implications when considered in the context of antibiotic resistance. This is not a new phenomenon which has emerged since the development of the early GMOs. It has been an issue for decades which has come to the fore in this decade. In view of the commercial drivers it is worrying that there is apparently no system which would highlight unacceptable techniques such as these. If their use could not be prevented, at least the likely consequences of non-authorisation could be flagged up, thereby highlighting the commercial risks of pursuing such a course.

27 May 1998

Letter from Professor John Durant Assistant Director (Head of Science Communication), National Museum of Science and Industry

The use of genetic modification (GM) in agriculture has been the subject of much public debate and not a little public dispute in Europe in recent years. My principal interest in the subject concerns the nature and significance of public perceptions of GM foods across Europe, particularly in relation to the policy-making process. For the past two years, I have been Contractor for a European Commission Concerted Action research programme on "Biotechnology and the European Public". This programme embraces a "Eurobarometer" random sample survey of public attitudes to biotechnology in all member states of the European Union (EU), together with parallel national studies of media coverage and public policy.

First, I should like to urge upon the importance of taking into account public attitudes towards GM in agriculture. The reasons for this are obvious: economically, the viability of GM in agriculture will depend upon the willingness of European consumers to purchase GM products; and politically, the viability of particular regulations of GM agriculture will depend upon their commanding at least a minimum level of public credibility and public support.

Attached, please find a short published report in *Nature* (*Appendix*) summarising some of the more striking findings from the most recent Eurobarometer survey on biotechnology. I should like to draw the ECC Sub-Committee D's attention to the following key points:

1. European attitudes towards GM as a whole are complex. Medical, plant and animal applications of GM attract widely differing levels of public support across the EU as a whole; and particular applications of GM attract widely differing levels of public support in different EU member states.
2. Across the EU as a whole, medical applications of GM attract most support, plant applications attract intermediate levels of support, and animal applications attract least support. The UK is fairly typical of the EU as a whole in this respect.
3. Across biotechnology as a whole, Finland, Greece, Ireland, Portugal and Spain tend to be most supportive; while Austria, Denmark, Germany and Sweden tend to be most critical. The UK occupies an intermediate position.
4. A decisive factor influencing levels of public support for particular applications of GM is public perceptions of the usefulness of these applications. Where applications are perceived as useful, they are generally also perceived as acceptable, irrespective of whether they are also perceived as being risky.
5. The reason why GM in agriculture attracts only moderate levels of public support is that significant numbers of people do not perceive it as being particularly useful. Those opposing GM in agriculture for this reason tend to be older, female, with lower levels of educational attainment and lower levels of trust in public authorities. Technical knowledge of biotechnology is not an important factor here.
6. The Eurobarometer survey (like other, even more recent surveys) suggests that the European public wishes to be consulted about GM and that it wishes to see clear labelling of GM food products. In the UK, for example, 55 per cent of the sample disagreed with the proposition that "biotechnology is so complex that public consultation is a waste of time"; and 82 per cent disagreed with the proposition that, "It is not worth putting special labels on GM foods". I suggest that the following conclusions may be drawn from our research to date:
 - (i) The public are currently rather ambivalent about GM in agriculture. Doubts about the real need for GM food products are serving to reinforce underlying anxieties about risk.

- (ii) The public are currently rather distrustful of many of the institutions (especially governmental and industrial institutions) that have responsibility for the provision and regulation of GM products.
- (iii) The public are strongly in favour of being given the opportunity to choose whether or not to purchase GM food products through clear and effective labelling.
- (iv) If industry wishes to secure public support for GM in agriculture, the most important things it should do are: first, to provide GM food products that possess clear and demonstrable consumer benefits; and second, to provide clear and effective consumer choice.
- (v) If government wishes to regulate GM in agriculture effectively, the most important things it should do are: first, to provide for effective public consultation in the course of policy-development; and second, to secure agreement with industry and consumer organisations on the provision of effective consumer choice. I trust that this evidence may be useful to the Lord Chairman of ECC Sub-Committee D and his colleagues as they conduct their investigation.

John Durant

8 June 1998

APPENDIX

EUROPE AMBIVALENT ON BIOTECHNOLOGY

Throughout Europe, there is widespread lack of trust in the ability of governments and other public authorities to deal effectively with people's concern about biotechnology applications.

BIOTECHNOLOGY AND THE EUROPEAN PUBLIC CONCERTED ACTION GROUP*

Many Europeans are uneasy about modern biotechnology, particularly about new genetic technologies. Although there is widespread support for "traditional" medical applications in the fields of diagnosis and treatment, few approve of the use of trans-genic animals for research or for applications such as transplantation of organs into humans (Fig. 1). There is also a striking mismatch between the traditional concern of regulators with issues of risk and safety, and that of the public, which centres on questions of moral acceptability. These are some of the conclusions to emerge from the latest Eurobarometer survey, designed to find out what people think about biotechnology (see box on following page). The main lesson of the survey is that public confidence in emerging applications of biotechnology cannot be taken for granted.

Conventional wisdom holds that knowledge is a crucially important determinant of support for science and technology—the more informed the public, the more likely it is to be supportive (see, for example, ref. 1).¹ But comparison of the new (1996) Euro-barometer survey with earlier ones in 1993 (ref. 2)² and 1991 indicates that although the public's knowledge of relevant basic biology has increased slightly, optimism about the contribution of biotechnology and genetic engineering to improving our way of life has actually declined. Furthermore, the new survey shows that knowledge is poorly correlated with support for all the applications described in Fig. 1.

Thus, as already discovered by other industries trying to introduce controversial technologies (such as the nuclear industry), more knowledge does not necessarily lead to greater public acceptance. But the situation with respect to biotechnology is more complex. The new survey suggests, for example, that people with greater knowledge are more likely to express a definite opinion about biotechnology; but this opinion can be positive or negative. It has been claimed that "mismatches" between scientific and lay assessments of risk are responsible for public resistance to new technologies.³ Public debates about some aspects of biotechnology have been dominated by the issue of risk, whereas in others moral considerations have been more prominent. Figure 1 shows that people see all biotechnology applications as potentially useful, but those involving crop plants, food production, the use of transgenic animals for research and xenotransplantation (trans-species organ transplants) are seen to involve risks; whereas only the use of transgenic animals for research and xenotransplantation are thought of as morally unacceptable. At first sight, this pattern implies that use, risk and moral acceptability are all likely to be strongly correlated with overall levels of support for specific areas of biotechnology.

Surprisingly, however, multiple-regression analysis indicates that although moral acceptability and use are strong predictors of support as measured by encouragement (moral acceptability, average $B = 0.54$; use, average $B = 0.35$, where B is an index of the strength of association), risk has very low predictive value (average $B = 0.04$). Only in the case of food production does risk perception appear to be more than a trivially small predictor of encouragement. The pattern of results across the six applications in Fig. 1 suggests that perceptions of usefulness, riskiness and moral acceptability could be combined to shape overall support in the following way. First, usefulness is a precondition of support; second, people seem prepared to accept some risk as long as there

* This article has been written by an international team of researchers working as part of a Concerted Action of the European Commission (B104-CT95-0043) administered on behalf of Directorate General XII by Andreas Klepsch. For details see box overleaf. Address for correspondence: G Gaskell, Department of Social Psychology, London School of Economics, Houghton Street, London WC2A 2AE, UK (e-mail: gaskell@lse.ac.uk).

¹ Evans, G and Durrant, J, *Public Understand Sci.* 4, 57-74 [1995].

² *Biotechnology and Genetic Engineering: What Europeans Think About it in 1993* (INRA (Europe), Brussels, 1993).

³ Bauer, M (ed.) *Resistance to New Technology: Nuclear Power. Information Technology: Biotechnology* (Cambridge Univ Press, 1995).

is a perception of usefulness and no moral concern; but third, and crucially, moral doubts act as a veto irrespective of people's views on use and risk.

The finding that risk is less significant than moral acceptability in shaping public perceptions of biotechnology holds true in each EU country and across all six specific applications described in Fig. 1. This has important implications for policy-making. In general, policy debates about biotechnology have been couched in terms of potential risks to the environment and/or human health. If, however, people are more swayed by moral considerations, public concern is unlikely to be alleviated by technically based reassurances and/or regulatory initiatives that deal exclusively with the avoidance of harm.

It is because of the issues of risk and safety that modern biotechnology is so extensively regulated in Europe. In the new survey, people were asked which bodies they thought best placed to regulate modern biotechnology (Fig. 2). On average, more Europeans preferred international organisations such as the United Nations and the World Health Organisation to either their own national or pan-European public bodies. Self-regulation by scientific organisations also rated highly. These results confirm the trend, observed by many others, of an increasing lack of confidence in national political institutions. They also show, however, that biotechnology is seen as having transnational consequences which national bodies are powerless to influence.

The survey highlights public concern that may have arisen as a result of lack of trust. For example, 74 per cent of respondents consider that genetically modified food should be labelled; 60 per cent believe that there should be public consultation about new developments in biotechnology; 53 per cent say that current regulations are insufficient to protect people from the risks of biotechnology; and 39 per cent think that religious authorities should be involved in the regulation of biotechnology. If biotechnologists and industry regulators are to command public confidence, they must incorporate openness and wide consultation into the policy-making process.

Do people discriminate among information sources for different issues? We asked people to select from a list of 12 institutions the one they thought most likely to be honest about two areas of modern biotechnology (Fig. 3). For new genetically modified food crops, people had most trust in environmental organisations, whereas for xenotransplantation people preferred the medical profession. Thus, people do discriminate among sources of information, and trust is strongly issue-specific. The medical profession remains one of the most widely trusted institutions within its own sphere of competence, as to a lesser extent do environmental organisations in theirs. National political institutions fare badly in public estimation.

In an increasingly complex world, it has been said that trust is a functional substitute for knowledge. Particularly in situations of high uncertainty, lack of trust could become an important determinant of the way issues are viewed: in the absence of trust, perceived risks and moral dangers proliferate and appear greater. For all three main groups of biotechnologies discussed here (medical agricultural/food, and animal experiments), people who express trust in public authorities tend also to have a systematically more positive view: they are more likely to say that biotechnology should be encouraged; to regard it as morally acceptable; and to view it as less risky. The largest effect of trust is found in the area of agricultural and food biotechnologies, which is of course highly relevant to current public debates on bovine spongiform encephalopathy (BSE) and genetically modified foods.

Thus far, we have treated Europe as if it were a single entity, which of course it is not. In Austria, for example, the opposite of the trend described in the paragraph above applies: those who express trust in public authorities tend also to express opposition to agricultural and food biotechnologies. Indeed, the Austrian government is explicitly opposed to the introduction of genetically modified foods such as soya and maize into the European market¹. The countries where support for the biotechnology applications described here is greatest are Portugal and Spain, followed by Belgium, Finland and Greece (shown in red in Table 1), whereas those where support is least are Austria and Germany, followed by Denmark, Sweden and Luxembourg (shown in blue).

Some national characteristics associated with support and opposition are shown in Table 1. In general (and with the significant exception of Finland), we find that the public in supportive countries tends to have low levels of contact, low levels of knowledge, a "menacing" image (see Table 1 footnote for explanation) and many expectations. There is also a relatively relaxed public attitude to risk and regulation. This is a pattern that we might expect to find in less industrialised countries that do not possess a well-developed biotechnology industry and where there is not much public participation in debate about biotechnology.

By contrast, the public in countries where most people oppose biotechnology tends to have high levels of contact, high knowledge, a matter-of-fact image and low-to-moderate expectations. At the same time, there tends to be public anxiety about risk and regulation. This is a pattern we might expect in more industrialised countries that possess a well-developed biotechnology industry and a relatively high level of public participation in debate. Once again, however, there are exceptions. Austria, for example, combines high contact with low knowledge and "menacing" image. (Apart from Austria, the countries where most people oppose biotechnology were among the first to introduce biotechnology regulations.)

Across the European Union, then, it seems that some countries in which biotechnology is best established are among the least supportive, whereas others in which the science and industry are in their infancy are the most supportive. This result is not as paradoxical as it appears: in the former group, familiarity with biotechnology

¹ Abbott, A, *Nature* 386, 745 (1997).

has provided greater opportunity for the emergence of concern; whereas in the latter, the potential economic importance of biotechnology is paramount.

However, it would be naive to pretend that the detailed pattern set out in Table 1 has easy or obvious explanations without a far better understanding of national cultures than surveys alone can provide. In Austria, for example, various factors, including general concern for environmental issues and a relatively recent encounter with biotechnology, coincident with anxiety over membership of the European Union, have conspired to raise the temperature of public debate about biotechnology almost to boiling point.

For now, it is perhaps enough to point out that these Eurobarometer findings echo the theme of the "risk society" as discussed by writers such as Ulrich Beck and Anthony Giddens^{1,2}. Like the European public in our survey, these authors do not find the language of objective risk assessment adequate arguing that risks are fundamentally moral and political. Our data suggest that large sections of the European public are deeply ambivalent about much of modern biotechnology. The prevailing focus of this ambivalence appears to be moral, a collection of anxieties about unforeseen dangers that may be involved in a range of technologies that are commonly perceived to be "unnatural".

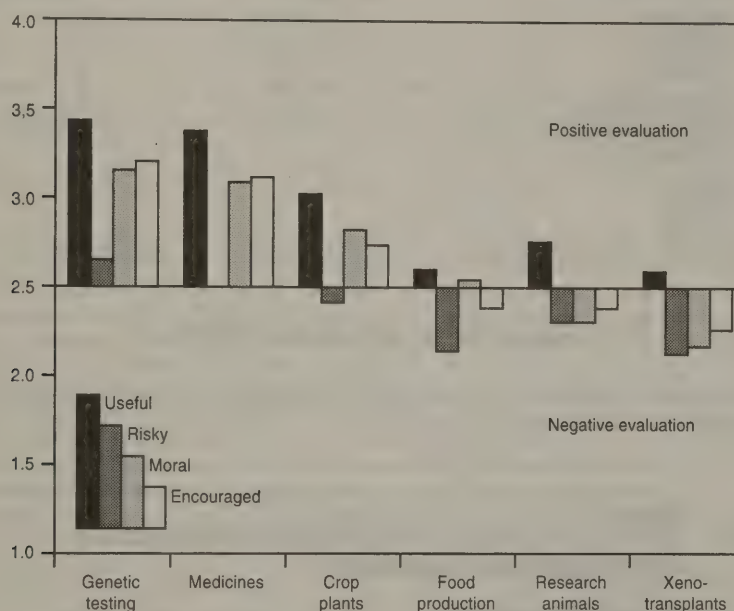


Figure 1 Perceived use, risk and moral acceptability as determinants of public support. Respondents were asked whether they thought each of six biotechnologies was useful (red), risky (green), morally acceptable (yellow) and whether it should be encouraged (blue). Mean scores across Europe are given on a four-point scale, in which 2.5 is the "neutral" point. Genetic testing, using genetic tests to detect inheritable diseases such as cystic fibrosis. Medicines, introducing human genes into bacteria to produce medicines or vaccines, for example to produce insulin for diabetics. Crop plants, transferring genes from plant species into crop plants to increase resistance to insect pests. Food production, using modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change in taste. Research animals, developing genetically modified animals for laboratory research studies, such as a mouse with genes that cause it to develop cancer. Xenotransplants, introducing human genes into animals to produce organs for human transplants, such as pigs for heart transplants into humans

EUROBAROMETER SURVEY

The Eurobarometer on Biotechnology (46.1) was conducted during October and November 1996. The survey conducted in each EU (European Union) country used a multi-stage random sampling procedure and provided a statistically representative sample of national residents aged 15 and over. The total sample within the EU was 16,246 respondents (about 1,000 per EU country). The survey questionnaire was designed by the authors as part of a larger study involving the comparative analysis of public perceptions, media coverage and public policy in relation to biotechnology from 1973 to the present.

Members of the Concerted Action who contributed to this article are: W Wagner & H Torgerson, Austria; E Einsiedel, Canada; E Jelsoe, H Fredrickson and J Lassen, Denmark; T Rusanen, Finland; D Boy and S de Cheveigne, France; J Hampel, Germany; A Stathopoulou, Greece; A Allansdottir, Italy; C Midden, Netherlands; T Nielsen, Norway; A Przystalski and T Twardowski, Poland; B Fjaestad, S Olsson and A Olofsson, Sweden; G Gaskell, J Durant, M Bauer and M Liakopoulos, UK.

The project is co-ordinated by M Bauer, J Durant and G Gaskell.

¹ Beck, U, *Risk Society: Towards a New Modernity*, (Sage, London, 1992).

² Giddens, A, *The Consequences of Modernity* (Cambridge Univ Press, 1990).

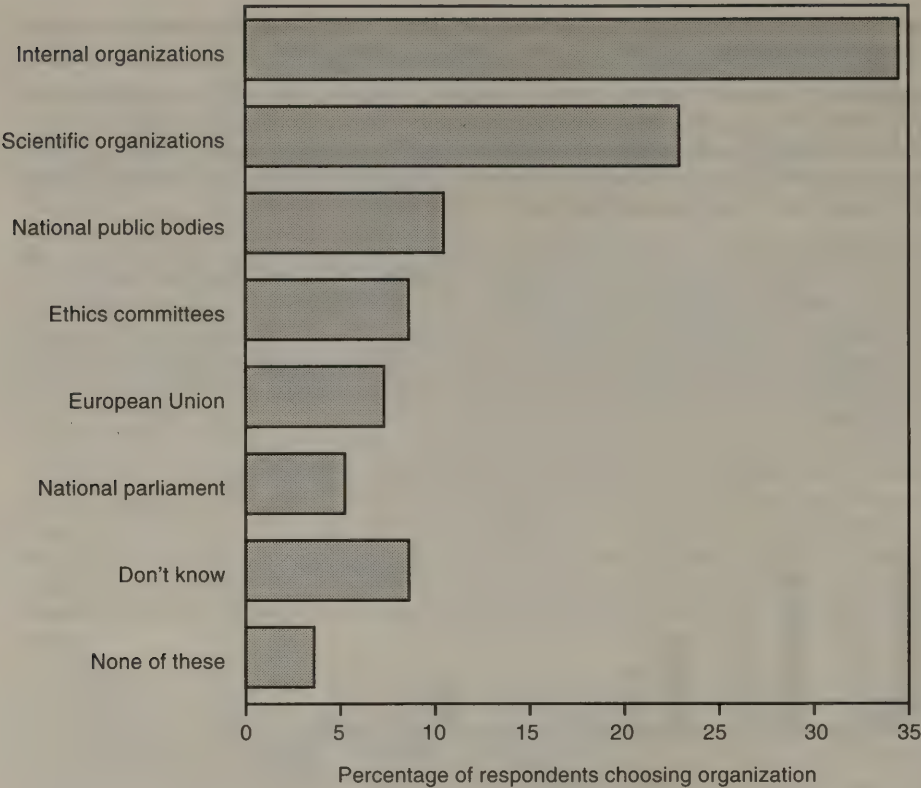


Figure 2 Who should regulate biotechnology? People were asked which of a selection of bodies they thought best placed to undertake this function

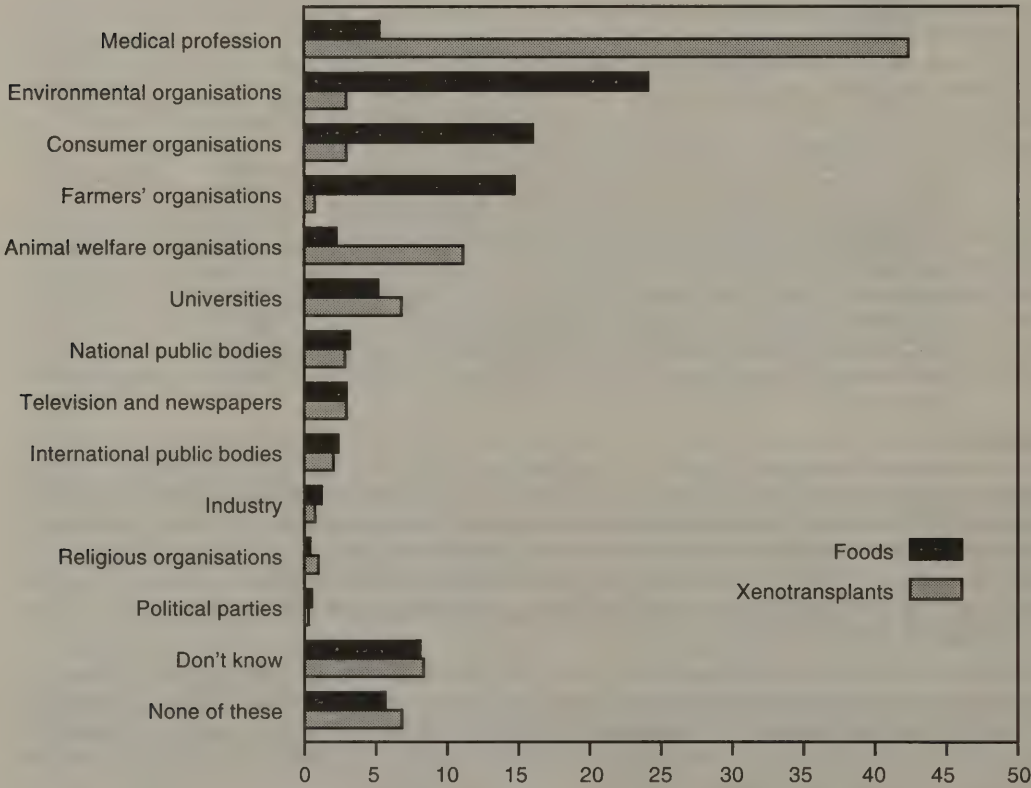


Figure 3 Who can be trusted to tell the truth about biotechnology? People were asked in which of several organizations they had confidence to tell the truth about new genetically modified food crops grown in fields (red) and the introduction of human genes into animals to produce organs for human transplants (green).

TABLE 1
National attitudes to biotechnology

<i>Attitudes to applications of biotechnology</i>						
Low encouragement Transgenic animals	A D DK Lux S UK IRL NL I B and FIN	F	GR E P			High encouragement Transgenic animals
Low encouragement Medical		A, D	DK LUX S IRL NL UK I F B FIN GR E P			High encouragement Medical
Low encouragement Agricultural and food	A D DK Lux S	F NL UK IRL I GR	B FIN E P			High encouragement Agricultural and food
<i>National characteristics</i>						
High contact	A D DK Lux S FIN	F I NL UK B	IRL GR F P			Low contact
High knowledge	DK S NL UK FIN	D Lux F I B	A IRL GR E P			Low knowledge
Matter-of-fact image	DK S NL UK FIN	Lux F I B E	A D IRL GR P			Menacing image
Low positive expectations	A D NL	Lux S I UK B GR FIN	DK IRL F E P			High positive expectations
Low negative expectations	A S NL FIN	D Lux DK I IRL B	UK F GR E P			High negative expectations
Anxious about risk and regulation	A S DK I F	D Lux B GR P	IRL NL UK FIN E			Relaxed about risk and regulation

Summary of aggregate scores for individual EU countries on a series of indicators in the survey. A, Austria; B, Belgium; D, Germany; DK, Denmark; E, Spain; F, France; FIN, Finland; GR, Greece; I, Italy; IRL, Ireland; Lux, Luxembourg; NL, Netherlands; P, Portugal; S, Sweden; UK, United Kingdom, Red, countries supporting biotechnology; blue, countries opposing it (dark shades indicate stronger support or opposition); black, mixed support and opposition. Top, countries are scored negative, neutral or positive on three main groups of biotechnological applications: transgenic animals (animals for research + animals for xenotransplantation); medical (genetic testing + medicines or vaccines); and agricultural and food (crop plants + food production). Bottom, countries are scored high, medium or low on six national characteristics.

"Contact" is derived from two questions designed to measure whether people had heard or talked about biotechnology before. "Knowledge" is based on a scale of factual questions about relevant basic biology. "Image" captures popular imagery associated with biotechnology. Respondents were invited to agree or disagree with propositions such as: "ordinary tomatoes do not contain genes while genetically modified tomatoes do"; and "by eating a genetically modified fruit, a person's genes could become modified". These questions were not primarily intended to capture levels of objective knowledge but to measure the extent to which respondents possessed menacing images of biotechnological products. "Positive and negative expectations" were based on a series of 10 paired questions describing a positive and a negative outcome of biotechnology that could happen in the next 20 years. A positive outcome was "curing most genetic diseases" whereas the negative one was "creating dangerous new diseases". Relaxed about risk means that respondents believe that current regulations are sufficient and agree that some risk must be accepted in the interests of economic competitiveness.

Memorandum by English Nature, Scottish Natural Heritage, Countryside Council for Wales and Joint Nature Conservation Committee

The statutory nature conservation agencies are concerned with the effects of GMOs on our natural heritage of native species and habitats, and has no locus on issues of human health and safety.

The UK has international obligations to safeguard its native biodiversity, through the EU Habitats and Species Directive, the EU Birds Directive, and the Convention on Biological Diversity. In the UK, biodiversity is often very closely associated with agricultural systems, and is already being affected significantly by agricultural intensification, with many formerly common farmland species having declined in numbers by up to 80 per cent. Use of GM crops has the potential to increase this pressure, and we believe there should be careful assessment of its implications on biodiversity.

POTENTIAL BENEFITS OF GENETICALLY MODIFIED ORGANISMS

The statutory agencies are not fundamentally opposed to the development and marketing of GMOs, as genetic engineering has the potential to solve some of the environmental problems associated with conventional intensive agriculture. However, we are concerned that the thrust of GMO development and marketing is presently concentrated on agricultural intensification and the continued use of biocides. We believe that there is a need for a more cautious approach and greater regulation of releases of GMOs if the benefits rather than the potentially damaging impacts are to prevail.

KEY RECOMMENDATIONS

1. Crop management systems for growing GM crops differ significantly from those of conventional agriculture

We recommend that the issue of GMO crop management and its effects on wildlife is addressed as a priority, both in terms of the need for more “forward look” research, and for the remit of the regulatory system to be extended to cover assessment of the ecological effects of crop management systems associated with growing GM crops.

2. Genetic modification of native plants and animals may increase the risk of gene introgression, and produce plants and animals which are capable of disrupting native ecosystems

We strongly recommend that insertion of genes into native species (or those which are introduced and have become widespread) should be strictly controlled by the regulatory process, with a broader and deeper risk assessment being required for proposed releases.

3. Crops modified to produce pesticides in their tissues may pose significant risks to food chains in agricultural ecosystems

We strongly recommend that throughout the EU all insect resistant (IR) crops which act by producing a biocide are subjected to statutory pesticide testing and monitoring. This testing should include an assessment of their potential ecological effects, and an assessment of risk to other species with which they might interact.

4. Some GMOs may have significant environmental benefits which need to be taken into account when assessing the potential overall effects of releasing them to the environment

We recommend that the regulatory process is extended to encompass assessment of potential benefits of the GMO to the environment. It may be possible to achieve this by extending the expertise and remit of ACRE.

5. To reduce the risks of multiple tolerance development, and to maintain the ability for ecosystems to act as natural “early-warning” systems, closer regulation of GMO crop management systems is needed, particularly at the farm level

We recommend that on-farm regulations are considered, aimed at ensuring that at least some sections of the crop are exposed to natural ecosystems during the growing season. It is difficult at this stage to see how this might be achieved for some crops other than by deliberately preventing the growing of crops with both IR and herbicide tolerant (HT) modifications together in the same crop. Further research into this area is needed.

6. Monitoring the environmental effects of growing GM crops is currently inadequate

We recommend that there is a need for statutory regulation and monitoring of GM crop management systems at the on-farm level unless and until there is clear evidence that such systems are viable, safe and sustainable. The results of such monitoring would provide valuable feedback to future risks assessments.

7. Post-release monitoring of cross-pollination, and identifying spread of GMO organisms into the natural environment, would be more effective if easily identifiable markers were inserted into modified gene sequences.

We recommend that consideration is given to a statutory requirement that easily detectable and safe markers enabling tracing of gene transfer to native plants are included in the GMO as a condition of its release.

8. No effective regulation of GM crop management is in place, and there is no provision for maintaining biodiversity by compensating for wildlife losses caused by more intensive GMO systems

A crop management compliance system covering commercial use of GM crops is needed. This could contain provision for a “cross-compliance” system where environmental compensation for intensification on some parts of an individual holding is put in place.

9. The GMO regulatory system is too narrowly focused on safety, and does not compare environmental audits of GMO systems compared with conventional crop management

Risk assessments are based on partially informed deductive reasoning and judgment. There is little or no independent input into them; they are prepared by those who have vested interest in seeing the crops receive approvals. We recommend that the regulations require independent assessment and comparison of the present crop system with that based around the GMO, setting out the agricultural and environmental benefits of both crop systems, and the environmental (and human) risks of each. In this way, regulation can be used to re-establish the link between product design and use (in crop management terms).

10. *The current regulatory system considers each application for release separately and on its own merits, and does not address the wider strategic issue of the cumulative effects of widespread use of GMOs*

Although we support the continuation of the case by case approach to the regulation of GMOs, we recommend that there should also be consideration of the cumulative environmental effects of widespread commercial and experimental releases. This is particularly topical in the case of GMHT crops, but should also be applied to other generic developments such as insect resistance.

11. *Approval of a GMO by the EU regulatory process does not allow for differences in the environments and ecosystems of member states*

For pesticides to be marketed, even though an active ingredient is approved for use at EC level, individual products need approval within individual member states, taking account of individual conditions of use such as the ecosystems which those products may affect. We recommend that the same principle should apply to GMO releases, enabling member states to take account of individual ecological and agricultural circumstances. This would need more explicit enabling clauses in the review of 90/220 EEC.

12. *The lack of ethical boundaries for the development and marketing of GMOs leads to high commercial and economic pressure on the regulation system*

A code of ethics is needed to set the framework for decision making and the domestic legislation delivering 90/220 EEC. It could set boundaries for research, development and marketing. This would help the industry to focus research, investment and development away from those areas which are unacceptable, and therefore reduce the economic pressures to gain approval for release.

13. *In view of the concerns expressed above, and the fact that a number of research programmes have been commissioned by MAFF and DETR to investigate environmental effects of GM crops, regulatory improvements need to take account of the results of this work*

As research into the environmental effects of GMOs is not due to report for another three to five years, and there is a need for further research, English Nature has called for a period of restraint on commercial releases until more is known. There is a continuing need for experimental releases for the purposes of such research.

1. THE DUTIES OF THE STATUTORY NATURE CONSERVATION AGENCIES RELEVANT TO THE REGULATION OF GMO RELEASES

1.1 English Nature is the statutory advisor to Government on nature conservation in England and was established by the Environmental Protection Act 1990. It promotes directly and through others the conservation of wildlife and natural features throughout the whole of England—the countryside, urban, coastal and maritime areas. Through the Joint Nature Conservation Committee (JNCC), English Nature works with equivalent organisations in Scotland, Wales and Northern Ireland. In fulfilling its duties English Nature advises Ministers on the development and implementation of policies for or affecting nature conservation; commissions and supports a wide range of research; and has a statutory duty when discharging its duties to take account of actual or possible ecological changes.

1.2 In common with the other nature conservation agencies, Scottish Natural Heritage, Countryside Council for Wales, and the Environment and Heritage Service (Northern Ireland), English Nature is consulted by DETR Biotechnology Unit on applications to release GMOs, including marketing applications from other member states. Most applications for releases of GMOs are in England.

1.3 The UK has international obligations to safeguard its native biodiversity, through the EU Habitats and Species Directive, the EU Birds Directive, and the Convention on Biological Diversity. In the UK, biodiversity is frequently very closely associated with agricultural systems and activities, and is already being affected significantly by agricultural intensification, with many formerly common farmland species having declined in numbers by up to 80 per cent. Use of GM crops has the potential to increase this pressure, and we believe there should be careful assessment of its implications on biodiversity.

2. POTENTIAL EFFECTS OF GMOs ON BIODIVERSITY AND GENETIC INTEGRITY OF NATIVE SPECIES—RECOMMENDATIONS FOR FURTHER REGULATION.

2.1 *Potential benefits of genetically modified organisms*

2.1.1. The conservation agencies are not fundamentally opposed to the development and marketing of GMOs, as genetic engineering has the potential to solve some of the environmental problems associated with conventional intensive agriculture. These range from potential reductions in the use of herbicides, fungicides and insecticides which harm wildlife, to the use of GMOs in pollution control. However, we are concerned that

the thrust of GMO development and marketing is presently concentrated on agricultural intensification and the continued use of biocides. We believe that there is a need for a more cautious approach, and greater regulation of releases of GMOs, if the benefits rather than the potentially damaging impacts are to prevail.

2.2 *Gene introgression or hybridisation*

2.2.1 Conventional plant and animal breeding may, over time, produce organisms which show similar characteristics (such as herbicide tolerance and insect resistance) to some GMOs. These traits are selected from the range of genes present in the gene pool of the native (or domesticated) organisms from which the breeding line is derived. As such, the selected genes have already been exposed to natural selection in the wild. If the selected line then back-crosses to the original line, there is no net addition to the existing gene pool. GMOs are different in that they contain genes which are derived from other, often very different, organisms. The genes within them do not occur normally in the gene pools of the original unmodified organism. These genes have not been exposed to selective pressures in the habitat of the original organism, and may have unpredictable effects if they outcross into wild relatives. Genetic modification also allows more rapid and radical modification of organisms than conventional breeding. We are therefore sceptical of the argument that GMOs are no different to conventionally bred organisms.

2.2.2 Work by Chèvre *et al.* (1997) in France [see Appendix 1 for references] has clearly demonstrated that gene flow between genetically modified (GM) oilseed rape (modified to express the *bar* gene) and native wild radish not only takes place, but that the hybrids are fertile and transfer the gene through successive generations. It is highly likely that similar gene introgression will be found for all releases of GM crops which are capable of out-crossing to native species. These would include sugar beet which crosses with native beet species. Sugar beet modified for herbicide tolerance (HT) is currently the subject of intensive commercial development.

2.2.3 Out-crossing to native species is likely to be a rare event, but with increasing acreages of GM crops, will occur more often. We are concerned not only about the possibility of HT hybrids becoming persistent weeds, and insect resistant hybrids having adverse effects on farmland insect biodiversity, but also that outcrossing risks harm to biodiversity in other semi-natural habitats. It is also possible that insect resistance in GM crops could transfer to native species, putting at risk species of insect which depend solely on that species. Some very rare insects are entirely dependent on a single plant species. One example is a small, endangered species of beetle which feeds only on the Lundy Cabbage, a rare wild brassica related to oilseed rape. We are also concerned about the possibility of other, as yet unknown, genetic modifications becoming incorporated into the genomes of other native species, mostly plants. The effects of these genes are not entirely predictable and pose an as yet unquantifiable risk to the genetic fitness (ability to reproduce) of native plant populations.

2.2.4 There is already gene flow from crops (and other plants including horticultural and decorative plants) produced by conventional plant breeding, to native plants, but the genes involved are of plant origin and produce traits found in natural plants. GM crops and other species contain genes of bacterial, viral and fungal origin, whose effects in plants other than the crop have not been considered.

2.2.5 There are existing experimental methods of genetically modifying plants which significantly reduce the risk of gene transfer, but these are not being developed as a commercial priority. The methods involve manipulation of genes conferring male sterility, and the insertion of genes into chloroplast DNA, which is inherited through the female line and not carried in pollen. They are not generally applicable to crops which rely on pollination for their commercial value, but it is possible that research into pollen compatibility systems will generate methods of reducing gene introgression even for these crops. The statutory nature conservation agencies would prefer such methods to be used in commercial systems whenever possible.

2.2.6 *If the regulatory process required that the risks of gene transfer were minimised during the developmental stage of the product, it would stimulate further research and development of these safeguards in many crops.*

2.3 *Crop management changes and potential effects of biodiversity*

2.3.1 There is no evidence that the new crop management systems associated with growing genetically modified herbicide tolerant (GMHT) crops will reduce overall herbicide use in the countryside. Even though GMHT crops may require fewer herbicide applications, there will probably be a large increase in the total area being sprayed, because certain broad spectrum herbicides would be used for the first time on growing crops like sugar beet and oilseed rape which were previously damaged by herbicides. The timing of herbicide applications may also shift to the growing season, when insects are in the larval or adult stages and require weed plant material to complete their life-cycles. Overall, we believe that the use of GM crops will further intensify arable agriculture, resulting in fewer wild plants and invertebrates within arable cropping systems. This will have huge impacts upon ecological food webs, and is likely to reduce further the already diminished and threatened populations of farmland birds, as well as species of arable plants which were previously common but are now rare. Increase in the use of broad spectrum herbicides would also have damaging effects on hedgerows, ditches and farmland trees, as a result of drift during spraying operations.

2.3.2 The known effects of intensive agriculture on farmland bird populations are documented by Campbell *et al.* in the 1996 review of the indirect effects of pesticides on birds, prepared for the Joint Nature Conservation Committee and the Department of the Environment by a consortium of experts, including the Oxford University BBSRC-NERC Ecology and Behaviour Group, The Royal Society for the Protection of Birds, and the Institute of Terrestrial Ecology. It is clear from this work that the crop management systems associated with intensive farming have serious adverse effects on 17 resident species of birds using farmland. We see changes in crop management associated with GM crops as having a greater potential effect on biodiversity than gene introgression. There is little, if any, research currently taking place on this issue, and the regulatory process does not include assessment of the ecological risks of GMO release.

2.3.3 The above discussion deals with the current wave of GM crop development, but we understand that there may be other novel GMOs already being developed by the Industry. These include modification of tolerances to adverse climatic factors, such as frost and drought, and soil conditions such as waterlogging, salt content and acidity. The introduction of these traits commercially may result in radical changes in farming practice, and further loss of wildlife. Conversely, GMOs may be developed to alleviate damage to wildlife in intensive farming systems whilst also increasing yield. This would release land for low intensity farming and nature conservation. We believe the regulatory system should positively encourage these latter developments.

2.3.4 *We recommend that this issue of changing farming practice and the effects on wildlife is addressed as a priority in terms of the need for more "forward look" research, and also that the remit of the regulatory system should be extended to cover assessment of the ecological effects of crop management systems associated with growing GM crops.*

2.3.5 In some European countries (e.g., Sweden, Norway, Austria and Denmark (Levidow 1997)) it appears that the remit of the Competent Authority already covers this issue. These countries have rejected approval of GMHT crops on the grounds that there would be significant adverse effects on the ecology of agricultural land, and that growing GMHT crops would be inconsistent with their goals of introducing integrated and environmentally friendly pest control.

2.3.6 A number of research programmes have been commissioned by DETR and MAFF to investigate some of the effects on biodiversity which may result from gene introgression and changes in crop management. The projects are listed in Appendix 2. Of 31 projects on GMOs commissioned by government bodies, 13 relate to potential environmental effects. These projects do not address all the concerns outlined above, and more field-scale research is needed to compare conventional with GMO crop management systems. It would, for example, be desirable to identify possible changes in weed density and insect biodiversity, and to investigate changes in crop rotation used in GMO management systems.

2.3.7 Even if the current research programme was broad enough, which we do not consider it is, the existing projects would not report until 2000 at the earliest. It may take another two years for this research to be integrated into other projects in Europe and elsewhere, and for the knowledge acquired from this effort to be used to inform the regulatory system. Applying the precautionary principle defined in the government's statements on sustainable development, it is difficult to see justification for the commercial release of GM crops until sufficient knowledge of their effects on the environment is understood.

2.3.8 *As current research into the environmental effects of GMOs is not due to report for another three to five years, and as additional research is also needed, English Nature has called for a period of restraint on commercial releases until more is known. There is a continuing need for experimental releases for the purposes of such research.*

2.4 Genetic modification of native plants and animals

2.4.1 Although it is difficult to obtain information about commercially sensitive research, we believe there is already advanced research on the insertion of high yield and HT genes into forage grasses such as rye-grass *Lolium perenne*. If these GM crops were released, even experimentally, there would be a risk that the genes might spread to native grasses by cross-pollination. The crosses (hybrids) and the original GM grass could be more competitive than native grasses if they invaded natural grasslands, and could not be controlled by the herbicides to which they are resistant. There is also the risk that use of HT grasses and other forage crops would lead to monocultural forage crops, with the use of broad-spectrum herbicides removing other grasses and herbs from diverse agricultural grasslands which currently harbour important populations of insects and birds.

2.4.2 There might also be other, unpredictable, effects of inserting genes into native plants, particularly if the GM plant could hybridise with a wide range of related native species. We are not aware of any current research programme specifically looking at the effects of gene introgression on the phenotypes of native species.

2.4.3 In a review of environmental risks posed by GMOs, Crawley (1996) considered that GMO perennials such as grasses and trees, rather than annuals, carried a high risk of invasiveness. We are concerned that applications for release of GM trees (e.g., poplar modified for lignin content) are already being received, and that research into genetic modification of other trees and shrubs is reported from several sources. Williamson *et al* (1996) argue that weediness (invasiveness) is very difficult to predict, and that the information used by the regulatory system in the EU is inadequate for risk assessment of invasiveness of transgenic hybrids.

2.4.4 We are equally concerned about reports that the US Department of Agriculture is sponsoring research in Florida which involves the release of predatory mites genetically modified to be resistant to insecticides. Modifications of native insects could carry risks of multiple resistance to insecticides being conferred on non-target species, and there is also the significant risk that they could be imported to other countries on crops with unpredictable and uncontrollable consequences.

2.4.5 *We strongly recommend that insertion of genes into native species (or those which are introduced and have become widespread) should be strictly controlled by the regulatory process, with broader and deeper risk assessments, and more detailed post-release monitoring, being required for proposed and licenced releases.*

2.5 Effects of toxins produced by GM crops on food webs

2.5.1 Recent research (Birch *et al* 1997, Hillbeck *et al* 1998, and Chèvre *et al* 1997) has demonstrated that the Bt insecticidal toxin inserted into insect resistant (IR) GM crops has adverse effects on non-target species, including ladybirds, lacewings and bees within farmland ecosystems. The magnitude of these effects, and their risks compared to conventional insecticide treatments, is unknown. We know little about the potential ecological effects of these genes in hybrids with native plants. It is possible that insect resistant hybrids would be fitter than native species and would spread in ecosystems, having deleterious effects on dependent insects (including those which are rare).

2.5.2 In view of the known effects of insect-resistant GM crops, and the fact that unlike most conventionally bred IR plants they produce chemicals which are highly toxic to insects, the regulatory authorities in the USA treat IR crops as pesticides, and subject them to the same rigorous testing that applies to chemical biocides.

2.5.3 *We strongly recommend that the same approach is adopted in the UK and throughout the EU, and that all IR crops which act by producing a biocide are subjected to statutory pesticide testing and monitoring. This should include an assessment of their potential ecological effects, and an assessment of risk to other species with which they might interact.*

2.6 Incentives to develop crops benefiting the environment

2.6.1 Besides the risks outlined above, GMOs have the potential to alleviate some of the more serious adverse effects of intensive agriculture on wildlife. Insect resistant GM crops, for example, offer a real prospect of reducing insecticide use on arable crops. Altering the growing characteristics of crops, e.g., shortening the growing season or changing the timing of harvests, offers the prospect of allowing more fallow land and less autumn planting. These developments could benefit bird and insect populations of farmland, whilst maintaining yields at current levels. However, present development and marketing is concentrated on those crops which yield high monetary returns, with little or no incentive delivered through the regulatory system favouring environmentally sound GMOs.

2.6.2 *The remit of ACRE appears not to cover consideration of potential environmental benefits when assessing whether a GMO should be released. We recommend that the regulatory process is extended to encompass assessment of potential and deliverable benefits of the GMO to the environment. It may be possible to achieve this by extending the expertise and remit of ACRE.*

2.7 Importance of intact farmland ecosystems

2.7.1 One of the arguments for maintaining viable ecosystems in direct contact with farmland is that species within these ecosystems can act as indicators giving early warning of potentially far-reaching environmental problems. Problems with the crop itself, or with its management, often manifest themselves before the system impacts on human health. Examples of this can be found in the impact of DDT on vertebrate reproduction which became apparent from effects on peregrine falcons and sparrowhawks (Ratcliffe 1970, Moore 1974), and the effects of aldrin and dieldrin on otter populations, where the pesticide (used in sheep dip and to control eelworm in potatoes) caused tumours and effectively prevented the animals from reproducing. This "early-warning" system has served agriculture well over the past 40 years. With the introduction of GM crops which are capable of IR and HT, crops may be managed out of contact with natural food chains, preventing any early warning of problems with either the crop or the management system.

2.7.2 *We recommend that on-farm regulations are considered, aimed at ensuring that at least some sections of crop are exposed to natural ecosystems during the growing season. Without further research, it is difficult at this stage to see how this might be achieved for some crops other than by deliberately preventing the growing of crops with both IR and HT modifications together in the same crop.*

3. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION

3.1 Research

3.1.1 We are concerned about the efficacy of the present system for the regulation of experimental releases. This is not a criticism of ACRE, but derives from legislative constraints on their remit. There is little direct consultation with neighbouring interests (which may include nature conservation) of the land concerned, and

several examples of failure to keep to cultivation and research protocols specified in the consent. In some cases, reported in various ACRE Reports and Newsletters, farmers and research stations were found by the Health and Safety Executive (HSE) to be disregarding the experimental protocols required in the release consent.

3.1.2 ACRE point out in their 1996–97 Annual Report that prevention of gene introgression and the development of multiple resistance to herbicides can only take place at farm level. For example, there would need to be minimum separation distances between crops with tolerance to different herbicides, to reduce the risk of hybridisation; any hybrids could be resistant to more than one herbicide and therefore be very difficult to control if volunteer plants became weeds. ACRE consider that this could be avoided by goodwill and good communication between farmers and seed merchants. On the evidence of non-compliance with conditions, set out in the previous paragraph, we have doubts about the efficacy of this recommendation.

3.1.3 *We therefore recommend that there is a need for statutory regulation and monitoring of GM crop management systems at the on-farm level, unless and until there is clear evidence that such systems are viable, safe and sustainable. The results of such monitoring would provide valuable feedback to future risk assessments. A crop management compliance system covering commercial use of GM crops needs to be put in place. This could contain provision for a “cross-compliance” system where environmental compensation for intensification on some parts of an individual holding is put in place.*

3.1.4 It is possible that future GMO development will produce entirely safe crops where gene introgression cannot occur. There is promise in the work of Daniell (1998) in Alabama, who reports that he has inserted an HT gene into chloroplasts which do not pass genes into pollen and therefore cannot be transferred to hybrids.

3.2 Release into the environment

3.2.1 We are concerned that the quality of risk assessments submitted by applicants is not adequate to allow a reliable judgment to be made as to whether the GMO should be released into the environment. In particular, there is rarely a detailed assessment of the likely effects on other organisms, despite mounting evidence that such effects exist and are potentially harmful to ecosystems. All assessments seen so far (over 50) have concluded, without real evidence (certainly not experimental evidence), that the risk to other organisms is effectively zero. This ignores recent research (Birch *et al.* 1997, Hillbeck *et al.* 1998) which demonstrates that the insertion of the Bt gene into crops has adverse effects not just on target organisms but also on their predators. Although these risks are clearly emerging from the few research studies specifically targeted at the effects of GMOs on ecosystems, risk assessments contain no comparison with the known risks from present intensive use of insecticides and herbicides.

3.2.2 Risk assessments are therefore based on partially informed deductive reasoning and judgment. There is little or no independent input into them; they are prepared by those who have a vested interest in seeing the crops receive approval.

3.2.3 *We recommend that the regulations should require an independent assessment and comparison of the present crop system with that based around the GMO, setting out the agricultural and environmental benefits of both crop systems, and the environmental (and human) risks of each. This system, in effect an environmental audit, should be incorporated within the regulatory process required by Directive 90/220. There is sufficient expertise in UK and European research institutes to co-ordinate and prepare such assessments, using evidence from research and monitoring on a global basis, and commissioning, or carrying out new research if necessary. In this way, regulation can be used to re-establish the link between product design and use (in crop management terms). Domestic legislation has been interpreted by ACRE to mean that the link between design and use is not part of their remit.*

4. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION AT UK LEVEL AND IN OTHER MEMBER STATES

4.1 Unilateral regulation of GMO releases to the environment at member state level is perceived as a restriction on competition and free trade. Approval for release and marketing in the EU is given by a qualified majority vote among member states. In effect this means that a GM crop which receives marketing approval for use in Southern Spain would have approval for marketing in Scotland. Clearly the crop would be grown among different ecosystems in each state, and therefore potential effects of gene introgression and crop husbandry systems would be different.

4.2 For those crops which rely on the use of biocides (e.g., herbicide tolerant crops), approval has to be given for the use of the biocide on the new GM crop before that crop can be used in the particular member state. Although this procedure might delay approval at member state level, it has little effect on the eventual approval of the new crop. There is provision under Directive 90/220 for member states to reject approval but they would need to be able to prove that the GMO has particularly high risks within the special circumstances of the member state. With the current paucity of research results on environmental effects, this would be very difficult to prove for the majority of GM crops.

4.3 Detailed proposals to review 90/220 EEC have recently been published by the EC as COM (1998)85. These proposals include provisions for:

- (a) approval of a new GMO by simple majority vote with member states playing a greater role;
- (b) an improved system of consulting Scientific Committees before approval;
- (c) common principles for risk assessment;
- (d) Seven years mandatory monitoring of GMOs after they receive marketing consent;
- (e) Better definition of the scope and provisions of 90/220, particularly by including consideration of all potential direct and indirect effects on the environment.

4.4 Whilst many of these proposals are welcome, in our view there are serious shortcomings:

4.4.1 The central principle that each GMO application should be assessed on its own merits remains unchanged. The "fast-track" procedure for approval of crops with generic modifications which have already been approved would also remain. These principles do not address possible cumulative ecological effects of multiple releases, each of which may appear to be relatively harmless. If the majority of agricultural crops were to carry the Bt gene, for example, there could be a much greater reduction in farmland birds and insects than that caused by current crop management systems. Similarly, widespread adoption of HT crops would have similar cumulative effects.

4.4.2 *Although we support the continuation of the case by case approach to the regulation of GMOs, we recommend that there is also consideration of the cumulative environmental effects of widespread commercial and experimental releases. This is particularly topical in the case of GMHT crops, but should also be applied to other generic developments such as insect-resistance.*

4.4.3 The risk assessment and information requirements still concentrate on the genetic modification itself and direct risks of release. There is no specific provision for Competent Authorities to assess the wider, indirect, risks to the environment.

Our views on these aspects of regulation are dealt with in previous sections

4.4.4 Criteria for selecting suitable monitoring regimes for the statutory seven year period are not set out. This is a difficult area, where the risks from new technology are ill understood, but it should be possible to define a minimum set of monitoring procedures which should be applied to GMOs after release. Williamson (1997) and others also point out that escape of GM genes may be irreversible, so even if monitoring detects ecological and environmental harm, it may not be possible to remedy every situation. However, it may be possible to build easily detectable markers into GMOs to facilitate detection and eradication. These would need to be quite different from the antibiotic-resistance markers currently used to develop GMOs, which are left in the final product.

4.4.5 *We therefore recommend that consideration is given to a statutory requirement that such markers are included in the GMO as a condition of its release.*

4.4.6 There is still the presumption that marketing approval given in one member state should apply throughout the EU.

4.4.7 *For pesticides to be marketed, even though an active ingredient is approved for use at EC level, each product needs approval within each member state, taking account of individual conditions of use such as the ecosystems which those products may affect. We recommend that the same principle should apply to GMO releases, enabling member states to take account of individual ecological and agricultural circumstances. This would need more explicit enabling clauses in the review of 90/220 EEC.*

5. THE MOST APPROPRIATE JURISDICTIONS FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

5.1 Given the current situation on GMO regulation, where each proposal for release is considered separately and on its own merits, a *code of ethics* is needed to set the framework for decision making and the domestic legislation delivering 90/220 EEC. This could operate in a similar way to codes on the development of human genetic research and development. It could set boundaries for research, development and marketing. It could, for example, discourage the high risk practice of inserting alien genes into native forage plants, but encourage research into GMOs which might have significant environmental benefits. This would help the industry to focus research, investment and development away from those areas which are controversial, and therefore reduce the economic pressures to gain approval for release.

8 June 1998

APPENDIX 1

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APPENDIX 2

Government research into genetically modified foods

Study	Research organisation
Tagging genetically engineered organisms	IFR, Norwich Laboratory
Development of new methods for safety evaluation of transgenic crops	BIBRA Toxicology International
Honey from genetically modified plants: integrity of pollen DNA, and expression of promoters in floral organs	Laboratory of the Government Chemist
Genetically modified organisms in food-evaluation of in vitro and in vivo models for assessing DNA transfer in gut	BIBRA Toxicology International
Detection of genetically modified organisms in foods	Laboratory of the Government Chemist
A model system for the quantitative analysis of horizontal spread of DNA from genetically engineered microorganisms GIT	IFR, Norwich Laboratory
Potential for gene transfer between manipulated bacteria and the resident microflora of the human gut	Rowett Research Institute
A model system for the quantitative analysis of horizontal spread of DNA from genetically engineered microorganisms	Surrey University
Regulation and targeting of transgene expression in fruit crops	HRI, East Malling
Causes of instability of transgenic plants	John Innes Centre
Safety of recombinant DNA technology: gene location, marker elimination and secondary effect	IFR, Norwich laboratory
Compilation of a database of oil compositions from new varieties of oilseeds	Leatherhead Food Research Association

Study	Research organisation
A database of novel foods and food products cleared in countries other than the UK	AEA Technology, Consultancy Services
Genes that have been introduced by genetic modification into crop plants intended for food use	AEA Technology, Consultancy Services
Persistent and potential infectivity of live bacteria in foods	IFR, Norwich Laboratory
Development of a strategy to promote the public's understanding of biotechnology	Sheffield University
The effect of agriculturally-relevant environmental factors on the expression and stability of genes affecting wheat lipases	University College Wales, Cardiff
Survival of DNA in the gut and the potential for genetic transformation of resident bacteria	Rowett Research Institute
Evaluating the risks associated with using GMOs in human foods	Newcastle University
Impact of transformation methods, construct and gene cassette architecture on the stability and expression of transgenes	John Innes Centre
Assessment of the risks of transferring antibiotic resistance determinants from transgenic plants to micro-organisms	Leeds University
Dissemination of GM DNA and antibiotic resistance genes via rumen microorganisms	Rowett Research Institute
Risk of gene transfer from genetically modified crop plants to gut bacteria	IFR, Norwich Laboratory
Gene expression in anthers and nectaries of transgenic plants	Leicester University
The stability of expression and inheritance of transgenes in brassica	John Innes Centre
Risk assessment of genetically engineered avian probiotics	Newcastle University
Possibility of <i>Agrobacterium</i> as a vehicle for gene escape	Mylnefield Research Services Ltd
Do protein sequences imply inter-species gene transfer?	Manchester University
The effect of background genotype on transgenes	John Innes Centre
Investigation of novel viruses created by growing viral coat protein transgenic sugar beet plants	Central Science Laboratory/IACR, Brooms Barn
Mobile genetic elements and lateral gene transfer events in crop species	Manchester University

Source: Hansard Issue No. 1772. Written answer given on 15 January 1998 (at Columns 292–293) by Mr Rooker to Mr Illsley, listing current and recently completed studies on genetically modified foods.

Memorandum by EuropaBio

1. It is essential for any revision of 90/220 that in addition to the necessary provisions for safeguarding human health and the environment, the Directive provides for a regulatory framework which enables biotechnology to play its full part in benefiting European society.

2. Modern biotechnology has a crucial role to play in the improvement of human and animal health and in agricultural practices for the benefit of the rural community and the environment: to mention but two areas where the potential contributions to European society are most advanced. Sound investment must be encouraged. The potential for employment is large (with an improvement in the business environment, the value of products and services using biotechnology in Europe could reach ECU 250 billion by 2005 and provide more than three million jobs).

3. As the Explanatory Memorandum to the revision of the Directive recognises “This growth sector has not yet reached its full potential and its cruising speed. In addition this new technology will maintain the

competitiveness of Europe on the world market and will make a major contribution to economic growth by enhancing the competitive position of industry and agriculture”.

4. Europabio's comments on the Commission proposals are therefore based on the requirement for a balanced package as expressed in the first paragraph, which also reduces trade friction to the minimum. Again, in the words of the Explanatory Memorandum “It is essential that regulation does not unnecessarily hinder the potential for technological innovation”.

5. The current 90/220 has not shown the ability to ensure that European society can utilise the benefits of biotechnology. It is subject to short-term political expediency. Any revision must deal with the need for stability, consistency and timeliness and be based solely on sound scientific criteria.

6. Europabio is concerned to ensure that the legislation is able to keep pace with rapid technological improvement. “International experience has shown that these figures, (i.e., number of product notifications), will increase rapidly in the next few years” (Explanatory Memorandum).

7. In conformity with the above, Europabio has been seeking improvements to 90/220 which:

- (1) Will enable the regulators to keep pace with the advances of the technology.
- (2) Reinforce principles of sound science.
- (3) Improve time lines and consistency of decision taking.
- (4) Relate properly to relevant vertical sector specific legislation.
- (5) Recognise the need for improved and streamlined procedures for specific applications and products based on the familiarity principle.
- (6) Recognise the principle of the internal market.

8. In its Memorandum to the revision proposals, the Commission recognises these concerns and has made proposals to meet all these criteria, with varying degrees of appropriateness. The following comments refer to required adjustments and Europabio's concerns with the new provision of a fixed term approval and for monitoring.

PROPOSALS FOR FURTHER IMPROVEMENTS:

Part B

9. The multistate procedure introduced in Part B does not make any distinction between Category I and Category II releases (Article 9). It should be possible to shorten the Category I procedure by a further 30 days.

10. The multistate procedure should be further developed so review by one Member State only is required for multistate trials.

11. A time-limit should be introduced concerning the public consultation period.

Part C

12. The proposed seven year authorisation period

13. The authorisation period should be unlimited. Should an unforeseen problem arise after authorisation, there is always the possibility for revising or withdrawing the authorisation (Article 22).

The seven year authorisation proposal is ill adapted to plant breeding. Improved varieties which incorporate the same event come on the market every year: therefore for all GM varieties which come on the market after the first year of Part C authorisation the period of normal certainty that a product can be commercialised is less than seven years, diminishing to one. *This is unacceptable.* The system of variety registration and the costs which go with it exacerbate the problem.

14. These comments also relate to the concept of fixed renewal periods. Normally they should not be necessary.

15. All phases of the procedure should be subjected to time disciplines, both by the Commission and the Member States. For example, time limits should be laid down for the deliberations of the Scientific Committee (Article 21).

16. Monitoring (Article 15). It is imperative that monitoring be targeted only to those issues which could constitute a risk from the GMO which is being authorised. There must be a link between the monitoring required and the safety assessment of the GMO. Monitoring should be restricted to possible ADVERSE effects which may derive from the genetic modification itself. It should be limited to that which is necessary for a company to fulfil its legal obligations under the directive.

17. Where the following categories fall within the scope of the Directive simplified fast Track procedures should apply:

- GMOs used for processing but not for cultivation in the European Union.
- GMOs developed by combining previously authorised GMOs by traditional breeding methods.
- new uses of GMOs previously approved.

18. Some definitions are open to different interpretations e.g., “placing on the market” (Article 2(4)). This definition continues to be too widely drawn and causes difficulties where GMOs are made available to third parties for research and other activities which fall short of actual commercialisation. These movements to third parties for research and other activities should be excluded from the definition.

3 June 1998

APPENDIX 1

INTRODUCTION

EuropaBio welcomes the explicit recognition in the Commission’s review (COM(96)630 final) that there are a number of problems with the operation of Directive 90/220 which need to be addressed.

Many of the conclusions concur with our own view that there is considerable scope—and, indeed, a pressing need—for improvement if Europe is to maximise the competitive benefits of modern biotechnology and secure Single Market objectives.

The need for change is pressing and recourse to lengthy legislative procedures should be avoided if at all possible. All the flexibilities of the Directive should, therefore, be exploited to the full to meet industry’s and academia’s requirements *before* embarking upon any wholesale revision of the Directive. In this connection we urge the Commission to explore the scope for maximum use e.g., of Article 6(5) and all other legislative instruments at the Commission’s disposal.

We have the following detailed comments on the Commission’s paper.

PART A—GENERAL PROVISIONS

Scope

Clarify the scope of this horizontal Directive with respect to other relevant sectoral vertical legislation, including Novel Foods since both are concerned, in part, with human health. Facilitate links to specific product legislation.

Clarify the status of hybrids between approved GMOs and address the considerable administrative burdens arising from event by event based regulation (Appendix).

Recognise the need to balance identified risks with benefits.

Introduce exemptions and accelerated procedures based upon EU and international experience with the same or similar products.

SOLUTION: the Commission should introduce these changes through appropriate administrative procedures backed, as necessary, by legislative instruments such as Commission Decisions.

Definitions

Clear and unambiguous definitions to the wide range of products covered by the Directive and detailed clarification are needed. For example, self cloned organisms should be exempted from the definition as is already the case with Directive 90/219.

International definitions should be used wherever possible to avoid any international trading problems and to simplify procedures for regulators and industry alike.

SOLUTION: the Commission should provide comprehensive definitions for all Member States and introduce changes through appropriate administrative procedures backed, as necessary, by legislative instruments such as Commission Decisions.

Risk Assessment Criteria

Use generally accepted criteria for safety based upon sound scientific principles. Harmonise the approach with that of the Novel Foods Regulation and other relevant EU legislation.

Overhaul the structure and functioning of the EU Risk Assessment Working Group to make it more effective.

SOLUTION: the Commission should develop and introduce urgently such risk assessment criteria, in collaboration with Member States, and taking into account other relevant international experience, e.g., OECD.

PART B—R&D RELEASES*(a) Risk categories and administrative procedures*

- (i) Implicit consent (comparable to notification procedures under Directive 90/219/EEC) should be introduced for GMOs which are known to be safe for human health and the environment via positive lists which can be updated annually.
- (ii) Plants, microbes and animals represent different levels of risk. A separate risk group for plants has been introduced. Further risk categorisation should occur for plants and for the microbe and animal groups.
- (iii) Ensure the 30 days SNIF consultation should take place within the 90 day examination period and not after it. Some Member States do not follow this procedure. The 90 day period must be respected to ensure Single Market objectives are met.
- (iv) Part B should be enriched by allowing for obtaining environmental clearances e.g., for seeds which are not intended for agricultural use but which are grown for industrial purposes (e.g., for pharmaceutical ingredients/use).
- (v) Considerable responsibility is vested with individual Member States under Part B with little opportunity for input into decisions from other competent authorities or the Commission. There needs to be greater Commission oversight and control to ensure that the objectives and requirements of the Directive are fully met and that the single market operates effectively.

(b) Simplified procedures

- (i) "Risk classes" should be introduced with differentiated provisions for release with and without prior consent as well as with implicit consent or "fast-track" systems reflecting experience. This should include "deregulated status".
- (ii) Precautionary measures such as mandatory monitoring should be reduced or ceased with increased experience. The experience from other Member States should be shared with those Member States authorising field trials of a GMO for the first time.

(c) Multi-state procedures

- (i) Multi-site and multi release provisions should be introduced with single consents and through harmonised risk assessment evaluations. This should be valid across Member States in standard formats (with an appropriate risk assessment).
- (ii) Harmonisation should be pursued through greater information sharing and e.g., mutual acceptance of data and decisions.

(d) Risk assessment

- (i) Risk assessment methodologies must not only have a sound scientific basis and respect international practice but should also be harmonised across Member States with clear guidance on what constitutes risk.

(e) Exchange of information between Member States

- (i) Any exchange of information between Member States should facilitate rather than delay permits and it should ensure the confidentiality requests of the notifier.

(f) *Link between experimental and product releases*

- (i) Data gathered under Part B already helps with assessments under Part C. A clear definition of data requirements under Part C will ensure that notifiers collect appropriate information under Part B. Limited area large scale releases should also be considered positively under Part B.

SOLUTION: All these improvements under Part B should be introduced through:

- appropriate administrative procedures;
- using the flexibility of Article 6(5); and/or
- where necessary, by legislative instruments such as Commission Decisions.

PART C—PLACING ON THE MARKET

(a) *Risk categorisation and administrative procedures*

- (i) Clarify the scope of the Directive and its relationship with other relevant sectoral legislation, including Novel Foods.
- (ii) Streamlined procedures and differential risk assessment and treatment should be introduced.
- (iii) The 90 day review period should be respected by all Member States.
- (iv) When dossiers are in the 60 day period objections should only be considered where they fall within the scope of 90/220 and to the case under examination.

SOLUTION: Introduce through appropriate administrative means backed, where necessary, by legislative instruments such as Commission Decisions.

- (v) Commission adaptation of its internal procedures to speed up proceedings is particularly relevant for the Commission drafting of decisions, the rate limiting steps of the current process. We do not consider that formal amendments are required to provide more expeditious case handling. A public commitment by the Commission to this would be seen as positive by Member States and industry alike—especially if backed by appropriate resources to implement the commitment.

SOLUTION: the Commission should give a public commitment to deal with cases expeditiously within challenging published set time frames and address the resource implications.

- (vi) Introduce more “transparency” into the proceedings and only entertain objections or queries from Member States up to 40 days into the 60 day period to allow the notifier to produce additional material and answers so that a decision can be taken within the 60 day period. This will help to reduce as much as possible the need to move to a further phase of the procedure.
- (vii) Fixed timings (28 days) should be formally introduced for the vote by the A22 Committee. 28 days is already standard procedure for decisions.
- (viii) A “fast track” system should be introduced for those products already properly evaluated and approved inside or outside Europe.
- (ix) A fast track procedure should be introduced for extensions of previously authorised products or similar products.
- (x) More transparency should exist when dossiers enter:
 - the 60 day;
 - Commission drafting; and
 - A21 Committee procedures.

All the timetables should be respected.

SOLUTION: Introduce through appropriate administrative means backed, where necessary, by legislative instruments such as Commission Decisions.

(b) *Risk assessment and scientific advice*

- (i) Establishment of harmonised risk criteria is necessary and must be presented as targeting control on areas of real risk (cf 90/219). In particular, harmonised understanding about what constitutes an adverse environmental effect should be secured in line with best international practice.

SOLUTION: The Commission should develop harmonised criteria urgently in collaboration with Member States, and taking into account other international experiences.

- (ii) Many Member states already have well respected Advisory Committees. The oversight of the EU scientific advisory bodies by DG XXIV and their interface with regulatory processes should lead to enhanced public credibility in the efficacy of the procedures and the decisions. It is important, however, to ensure that such EU scientific bodies do *not* add another level of bureaucracy which could introduce further delays.

SOLUTION: Consideration should be given to the interface of the various Scientific Advisory Committees with the regulatory processes.

(c) *Labelling*

Standardised labelling procedures are necessary between Directive 90/220, the Novel Foods Regulation and Feeds regulations etc., (to come).

SOLUTION: EuropeBio members have already taken an initiative on voluntary labelling and other relevant product information under Direct 90/220. This voluntary approach will continue until it is subsumed by implementation of the legislative amendment using the Directive's flexibility.

(d) *Confidentiality*

Confidential and sensitive commercial information and the status of notified dossiers should be respected.

PART D AND ANNEXES

It is necessary to provide for regular adaptation of all annexes through a Regulatory Committee procedure.

SOLUTION: Introduce through administrative means backed, where necessary, by appropriate legislative instruments such as Commission decisions.

APPENDIX

REGULATORY IMPACT OF CONTEMPORARY DEVELOPMENTS IN PLANT TRANSFORMATION

One of the major barriers to efficient application of biotechnology for the improvement of many of our major crop species has been difficulties with most important elite genetic lines (i.e., the progenitors of commercial varieties) to regenerate fertile plants in tissue culture. Developers of genetically modified crops have, generally, been forced to transform non-elite lines that are amenable to regeneration. Elite lines must then be "converted" by crossing in the transgene followed by several generations of back-crossing. The resulting converted elite line must be re-tested to ensure performance has not been impaired. But back-crossing still results in a significant delay in bringing the new transgenic variety to the market.

More and more of the most important elite lines of germplasm are, however, now proving amenable to transformation and regeneration (i.e., elite transformation). This offers developers the opportunity to introduce a new trait directly into many of the current leading commercial varieties, without any undesirable linked genetic material, resulting in more predictable performance, reduced need for testing and accelerated product development.

However, such elite transformations will place significant additional burdens on the current regulatory oversight systems that are based on "event by event" regulation. Instead of reviewing and approving one event that will be used to develop many varieties, each new variety will constitute a new event that must be reviewed. The consequent resource implications for both regulators and developers are obvious. Unless a more flexible approach to product approval is adopted, for example, a gene by gene approach, the regulatory system will become a serious impediment to product development and to Europe's competitiveness in agricultural plant biotechnology.

Memorandum by the Food and Drink Federation

1. POSITION OF THE FOOD MANUFACTURING INDUSTRY

1.1 The Food and Drink Federation (FDF) is the leading representative of the UK food and drink manufacturing industry. Our interest in genetic modification in agriculture is therefore as users of primary produce as a basic raw material for our products. In order to meet the needs and demands of our customers, be they further down the processing chain, retailers or end consumers, our members need to ensure a supply of safe, wholesome raw materials at acceptable prices all year round, taking account of seasonal availability.

1.2 In our response to the Select Committee on Science and Technology's inquiry into the Regulation of the UK Biotechnology Industry and Global Competitiveness (April 1993), we stated that the use of genetic modification (GM) for precision breeding of food crops to introduce defined improved traits could offer benefits to agriculture, manufacture and consumer appeal: reduction in the need for pesticides in agriculture and distribution; reduced fertiliser needs; more efficient use of enzymes in processing; better product shelf life in distribution and the home; better product flavour and texture.

1.3 This remains our position on the use of this technology, but in the five years since the previous inquiry many developments have taken place, notably the introduction of the first GM products on the supermarket shelves; the importation of the first GM commodity crop from the USA; the implementation of EC Regulation No 258/97 concerning novel foods and novel food ingredients; and the impact on consumer confidence in the food supply of the 1996 BSE crisis.

1.4 This chain of events has caused us to scrutinise very carefully the implications for the food manufacturing industry of further planning of GM crops, not least because of pressure in our own sector from retailers, consumer and environmental groups. Our views with regard to the regulation of genetic modification in agriculture, whilst based on scientific principles, will necessarily be tempered by commercial and political pressures.

2. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION

(a) *Research*

2.1 FDF is not directly involved in research in this area. However, agricultural competitiveness and food cost and quality are directly related. It is therefore important to our industry that the agricultural research base is at the cutting edge of science and technology whilst firmly adhering to the principles of safety and good environmental practice.

2.2 FDF understands that the application of directive 90/219 on the continued use of genetically modified organisms, implemented in the UK by the Genetically Modified Organisms (Contained Use) Regulations 1992, has impacted on plant breeding at R&D level though the Directive was intended to control micro-organisms only. As more than 20 years' experience has now been gained, it would be appropriate for legislation in this area to be reviewed in the light of developments and understanding of the technology and a history of safe use to simplify and rationalise accordingly. Regrettably, public mistrust of the use of genetic modification in food and agricultural production will inevitably result in any changes to the legislation being politicised instead of updated in recognition of improvements in the understanding of the science.

(b) *Release into the environment*

2.3 FDF monitors the work of the advisory Committee on Releases into the Environment (ACRE) and has held discussions with its Chairman, Professor John Beringer. FDF has been impressed by the professionalism of ACRE and the Committee's refusal to become embroiled in issues outside its statutory remit. ACRE's decision and reports are an excellent source of information for our sector of the industry and we understand its work to be generally respected. Its recent decision to "name and shame" a number of companies who were in breach of their field trial conditions is applauded as a reflection of the Committee's assiduousness, impartiality and transparency.

2.4 Following adoption of the Regulation on novel foods and novel food ingredients (258/97) in January 1997, it was clear that Directive 90/220 on Deliberate Releases to the Environment would need to be updated in respect of marketing consents where provisions had been superseded by Regulation 258/97. However, as with Directive 90/219, the Directive has been politicised and procedures are being rendered more onerous on grounds of safety and potential environmental damage, though no such grounds have been demonstrated. Opponents of the technology cite the BSE crisis and the "precautionary principle" as the basis for exercising caution. Such an approach risks impeding agricultural progress and competitiveness in the EU whilst having no effective influence over developments elsewhere. The food manufacturing sector risks being disadvantaged, not to say confused, in international markets and global trading situations where it is unclear whether or not a GM crop has been authorised for use or growing in the EU. The very different approach to the regulation of GM crops in North America means that a number of varieties are already being grown and traded there. In the event of a GM crop not being authorised for release under 90/220, but known to be commingled with the conventional supply, we would be prevented from buying from that supply. However, in the case of oilseeds, for example, there would be nothing to stop oil produced from that crop being imported into Europe, or indeed any food product in which it was used as an ingredient. Such a situation risks serious trading difficulties, as well as threatening the competitiveness of the UK (and EU) processing industry.

2.5 We are frequently asked by our members about the status of authorisations of GM varieties and are unable to offer advice unless we have direct contact with the seed company seeking the authorisation or the Commission Decision has been published. This is a reflection of the frustration experienced when knowing that a particular GM variety is under development and that approval for growing/marketing in the EU is being

sought, but without any idea of when it might come on stream. Applications disappear into the EU bureaucracy for months, leaving our sector of the industry unclear as to what preparations should be made for the handling of a new GM crop, with all the inherent customer concern that entails. If clearance procedures cannot be speeded up, arrangements should be made by the Commission to issue regular status reports on applications in the pipeline. FDF supports the procedure adopted by ACRE and UK attempts to simplify procedures at EU level in line with ACRE's practice and experience.

(c) *Novel Foods and their labelling*

2.6 FDF believes that the use of genetic modification of food production can provide benefits throughout the food chain: to primary producers; food processors and consumers. As stated in our evidence to the previous Select Committee inquiry (ref. paragraph 1.2 above), we do not believe that genetic modification per se presents any food safety risk or that foods produced using GMOs represent a special class of new foods, and that we believe they should be subject to the same type of risk assessment as any other new food product and its intended use, rather than its method of development. Therefore, we supported the need for European legislation covering the introduction of any novel food, whether or not GM origin, as a means to achieving a harmonised approach to the risk assessment of all novel foods and ensuring consumer confidence and fair trade.

2.7 Unfortunately, during its nine year gestation period, the eventual Regulation on novel foods and novel food ingredients (258/97) became increasingly subjected to political compromise, particularly with regard to labelling requirements, and the final text, whilst welcomed by industry as a necessary legal instrument in an increasingly difficult market situation, was in many respects unclear, incomprehensible and open to interpretation. It left many uncertainties, not least how to deal with those products of genetic modification already on the market, specifically Monsanto's RoundUp Ready™ soya and Novartis's Bt maize.

The labelling of foods containing derivatives of these raw materials was resolved only after lengthy debate, as recently as 26 May, and after industry voluntary labelling agreements had already been put in place in several EU Member States. This recently adopted Regulation, which supersedes Commission Regulation (EC) No 1813/97, is effectively an interpretation of "substantially equivalent" (Article 3.4 of Regulation 258/97) and will therefore have a significant impact on the application of 258/97 to future submissions for approval and as such is likely to act as a deterrent to potential applications, imposing more onerous procedures on foods or food ingredients which might hitherto have been regarded as "substantially equivalent" to the conventional product. This in turn will have implications for applications under 90/220.

2.8 FDF has always maintained that, by any reasonable criteria, food crops genetically modified for agronomic benefit, i.e., herbicide tolerance or pesticide resistance, are equivalent to conventional crops, i.e., the final food product, as sold to the consumer, does not differ in safety, nutritional composition, functionality or taste. Equally, we have maintained that consumers should be informed about the use of this new technology in the food supply and to this end have been running a consumer information campaign, "foodfuture", since 1995. Labelling can never be a substitute for consumer education and it is debatable what message the indication on pack that a product contains genetically modified soya or maize will convey. FDF supported the labelling criteria established by Directive 258/97, in particular where genetic modification resulted in any change in composition, nutritional value or nutritional effects or intended use of the food which rendered a novel food or food ingredient no longer equivalent to an existing food or food ingredient. We anticipated that the criteria used to assess "equivalence" would be based on the OECD concept of substantial equivalence.¹ The Council Regulation concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC² has now established a legal precedent for an EU definition of "substantially equivalent" which is NOT based on internationally accepted criteria.

2.9 Whilst we in no way wish to deprive consumers of information they consider to be relevant to their purchasing decision, indeed industry announced its intention to introduce voluntary labelling guidelines from January this year,³ we are opposed to the introduction of legislation which preserves in aspic a concept which may have relevance for a short period only. Soya derivatives in particular are used in a wide range of products in very low amounts. The actual GM content in any product will be very small, given that the commodity crop is commingled. The first GM soya crop, harvested in the USA in autumn 1996, represented only about 2 per cent of the total harvest. Whilst the proportion of GM crop in the total harvest is steadily increasing, the GM ingredient still represents only a tiny fraction of the product as a whole. This cannot be conveyed to consumers by use of a pre-determined brief indication on a label, but will result in a large number of products being labelled. We believe this will detract from any future labelling of GM foods or ingredients where a real *difference* in the product is indicated, thereby causing consumer confusion. It will also introduce an additional burden on industry in terms of product testing and analysis. Moreover, the Regulation has been put in place without agreement on validated methods of analysis or thresholds for "adventitious contamination".

¹ Concepts and principles underpinning safety evaluations of food derived from modern biotechnology. EOCD Group of National Experts on Safety in Biotechnology; COM/ENV/DST/EC/BT(91) 80/Rev 1; 1992.

² Council Regulation (EC) No. 1139/98, Official Journal of the European Communities, 3 June 1998.

³ BRC/FDF/IGD press release, 20 November 1997.

2.10 Included in the general principles of labelling are that it must be accurate, truthful and meaningful. It must also be enforceable. We do not believe that the Regulation can be properly enforced throughout Europe until validated methods of analysis of both DNA and protein differences resulting from the presence of RoundUp Ready™ soya of Bt maize have been established. We have always been opposed to “negative” labelling, i.e., “free from genetically modified. . .”, but some retailers and manufacturers are sourcing soya from assured non-GM supplies for certain lines. Whilst every care is taken, to ensure that no GM material is present by means of audit trails throughout planting, harvesting and transportation, the possibility of detecting modified DNA cannot be entirely dismissed for example because of the possibility of wind or insect pollination from a GM crop grown elsewhere. The Regulation takes account of this, but agreement on thresholds for such “adventitious contamination” has not yet been reached.

3. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

3.1 Both industry and consumers are currently in a transition period with regard to the introduction of foods and ingredients produced by GM. It is our belief that the technology offers potentially enormous benefits throughout the food chain, but that consumers are unlikely to accept the technology unless it offers direct benefit to them. The difference in consumer reaction to the introduction in 1995 of GM tomato purée contrasted with the 1996 reaction to the importation and use of the first GM soya is indicative of this, though may also reflect the plummeting in consumer confidence in the food supply following the March 1996 BSE crisis. We find it regrettable that the complexities of international commodity trading have imposed a product on the British (and European) public before it was ready, creating enormous difficulties in the food supply chain as a result, but we cannot isolate ourselves from the rest of the world and the realities of global trading. The more EU legislation diverges from that of the USA, Canada and South America, the greater will be the difficulties in sourcing raw materials acceptable in the EU market. This is likely to place an added financial burden on industry, and consequently consumers, without achieving any tangible benefit. The introduction of GM soya has demonstrated that we are unlikely to be able to achieve any significant influence on American growers. Restrictive EU legislation will serve only to disadvantage our own.

4. THE MOST APPROPRIATE JURISDICTIONS (INCLUDING INTERNATIONAL REGULATION AND HARMONISATION) FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

4.1 On the assumption that this question refers to the safety of GMOs, we are confident that existing regulations in North America and the EU ensure safety both at research level and in application. We are unfamiliar with regulation in the Far East, particularly China, where we understand that the use of GM in the food supply is developing fast. We believe that global trading situations make it imperative that the same risk-based approach to the use of GM in the food supply be adopted internationally. This might best be done via the UN's Codex Alimentarius, through lengthy bureaucracy may well frustrate rapid agreement.

5. THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION

5.1 Provided legislation is equitably enforced, European legislation should establish a level playing field throughout Europe. Our competitiveness is more likely to be threatened in international markets if over burdensome legislation increases the comparative cost of European production. There is a risk that R&D, and indeed food production, will be moved out of Europe if over-regulation resulting from reaction to short-term political pressures increases costs and impedes development without enhancing consumer or environmental protection.

4 June 1998

Memorandum by GeneWatch

THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION OF:

(a) *Research*

1. GeneWatch believes that the shortcomings in the way in which research into genetically engineered organisms (GEOs) is regulated include a lack of due attention to the final commercial intentions of the research and the lack of adequate research on long term hazards.

2. The commercial reason for undertaking research involving the release of GEOs should be taken into account in assessing risks. Whilst small scale experiments may appear to pose a minor or negligible risk, the impacts on a commercial scale will be on a much greater. An assessment of the risks in the context of intended use would aid in identification of the information required to evaluate hazards at an early stage and ensure that

the appropriate data was available to assess risk when a commercial application was made. This should improve the *quality* of the research by ensuring experiments are properly designed and likely to achieve their objectives. If it was clear that a commercial use would not be acceptable or that the overall research programme did not address the risks in a rigorous way, experiments should not be allowed. Such an approach would improve the efficiency as well as the safety of the system.

3. For example, when the first application is made to test, say, an insect resistant plant the data requirements for evaluation of a commercial scale should be identified. The benefits of having this approach to research can be seen from problems which have already arisen but could have been avoided. In the case of the Novartis insect and herbicide resistant maize which also contains an ampicillin resistance gene, a research plan should have been produced following negotiation between the authorities and the company to ensure the appropriate data would be provided to allow a robust and agreed decision on marketing. The continuing controversy and dispute between member states of the European Union might have been avoided if it had been made clear at an early stage that detailed justification for the inclusion of an antibiotic resistance gene was needed,¹ that the potential of secondary impacts on non-target species would have to be fully investigated,² and research to develop a resistance management scheme was required.³

4. Having such an evaluation of research requirements at an early stage would help address the lack of research on long-term hazards to health, the environment and agriculture. Most experimental field trials of GE crops focus on agronomic traits such as yield leaving other effects such as invasiveness less rigorously addressed⁴. Although small scale experimental field trials will always have limited ability to answer questions about large scale commercial use⁵, they could be made more scientifically rigorous. For example, studies have shown that experiments to investigate the potential for GEOs to be invasive need to be undertaken for at least three years however many sites are used⁶.

5. GeneWatch believes that the proposed revisions to the Deliberate Release Directive (90/220/EEC) should include provision for the identification of basic research requirement for commercialisation at the initial research stage.

(b) *Release into the environment*

6. The fundamental problem with the Deliberate Release Directive is that its scope has been defined far too narrowly. This is particularly evident at the stage when companies are applying for consents to market GEO. Not only have there been disputes between member states about *all* applications to market GEOs, but the regulations do not satisfy either the industry or Non-Government Organisations. The report of a series of workshops held in 1995 identified the serious mismatch which exists between the construction of the risks under the present regulations and the way in which industry and NGOs consider the risks. This is appended at Appendix I. The same mismatch between the regulations and the public's concerns about GEOs was found in research into public attitudes towards GE foods. This is appended at Appendix II (not printed). Unless this mismatch is corrected, public confidence in the regulations will never be achieved.

7. The present regulatory approach is to assess releases on a case-by-case basis, using data from small scale experiments to determine safety. The focus is on the GEO and the immediate changes to the organism. Whilst recognising the importance of this aspect, GeneWatch believes that the wider impacts on the environment and agriculture should also be borne in mind when evaluating the risks of GEO. For example, it is questionable whether the use of herbicide resistant crops is beneficial, because the use of certain chemicals will increase and complex weed problems may be created resulting in other chemical herbicides being used. The cumulative impacts on the environment and agriculture of more and more GEOs are also neglected in the Deliberate Release Directive. For example, as more and more insect resistant crops are used there may be harmful effects on non-target insects and the birds that rely upon them for food. Looking at each application in isolation from the others tends to make these sorts of risks seem unimportant as the "big picture" is ignored. Although the industry feels that the potential benefits of GEOs are not addressed, GeneWatch believes that there is a

¹ The presence of an ampicillin resistance gene in the Novartis maize led the UK's Advisory Committee on Novel Foods and Processes to recommend that the maize should not be used for human or animal food. This was because of the risks of the resistance gene being transferred into bacteria in the intestine and compromising antibiotic therapy. The concerns of the UK were over ruled by the Commission but have led to Austria and Luxembourg imposing bans on the Novartis maize.

² A paper has recently been published (Hilbeck, A *et al* (1998) *Environmental Entomology* 27: 480-487) that indicates that non-target species of insect can be harmed by ingesting the toxin in the Novartis maize. These sorts of risk had been identified long ago and the research needs could have been identified in advance. If Novartis had addressed these issues in more detail, the controversy may have been avoided.

³ The Commission are developing a monitoring plan to investigate whether insects are developing resistance to the *Bacillus thuringiensis* toxin in the maize. The monitoring will be carried on the maize used commercially but it is possible that the same data could have been collected on an experimental scale rather than allowing a large scale experiment to take place in the environment.

⁴ Rissler, J & Mellon, M (1996) *Perils amidst the promise*. Union of Concerned Scientists: Washington DC.

⁵ Williamson, M (1996) Can the risks from transgenic crop plants be estimated? *Trends in Biotechnology* 14: 449-450.

⁶ Kareiva, P, Parker, I M and Pascual, M P (1996) Can we use experiments and models in predicting the invasiveness of genetically engineered organisms? *Ecology* 77: 1651-1675.

“taken-for-granted” assumption behind the risk assessments that GEOs represent positive progress for agriculture¹.

8. To address the mismatch between public concerns and the present regulatory system, GeneWatch believes that the revision of the Deliberate Release Directive must allow for:

- an evaluation of the public benefit of releases of GEOs through an evaluation of their effect on sustainable agriculture;
- an assessment of the cumulative impacts of commercial scale releases through an evaluation of the hazards of each class of crop (e.g., herbicide, insect and disease resistance) which should take place before individual applications are considered
- a mandatory segregation and monitoring scheme throughout the food chain to allow for tracking, the early identification of problems and consumer choice;
- a system of compulsory liability for any damage to the environment or human health arising from the use of a GEO.

(c) *Novel foods and their labelling*

9. The Novel Foods Regulation has failed to ensure a labelling system for GEOs which takes into account the means of production. Attached as Appendix III is a briefing GeneWatch has prepared on this subject. (*not printed*).

10. Only foods which contain foreign DNA or protein as a result of the genetic modification come within the scope of the Regulation. Therefore products of GEOs which do not contain these will be exempt from mandatory labelling. This will exclude, for example, oil from crops such as oilseed rape and soybean and which are found in a very large number of GE foods. This restriction on labelling is based on the assumption that it is only when foreign DNA or protein is present in food that a label can be justified on “scientific” grounds as these alterations are the only source of any health risk. This narrowing of the scope fails to allow people to make a choice based on an evaluation of the whole technology and its dangers not only to health but the environment and the course of agriculture. Using the logic behind the Novel Foods Regulation, free range eggs would not be labelled as their chemical composition is the same as factory farmed eggs.

11. Such a limitation on consumer choice is clearly unacceptable, especially given the depth of public concerns about GE.

12. GeneWatch believes that only comprehensive labelling can fulfil consumers’ rights to make choices about what they eat. This is dependent upon the introduction of a statutory segregation scheme for GEOs at all stages to allow food producers and retailers to produce reliable information about the contents of foods.

THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

13. In Europe, Member States have experienced considerable difficulties in reaching agreement on decisions whether to allow the marketing of genetically modified organisms (GMOs) under Part C of 90/220. Every application has been disputed and the French Government has now introduced a moratorium on the commercial use of GMOs while a public consultation takes place. This has further highlighted the problems and confusion.

14. The disputes and therefore the low efficacy of the regulation stem, in part, from differences over the interpretation of the scope of the Deliberate Release Directive. Some Member States such as Austria and Denmark include indirect effects on agriculture as part of the risk assessment. In addition there are differences in how “harm” is defined between Member States. Much of this comes down to different value judgments about whether, for example, genetic pollution matters and whether current agricultural practices form the base line against which to judge something as harmful or not.

15. GeneWatch believes progressive standards should be set to help remove some of the points of disagreement to reflect the intended precautionary nature of the regulations relating to GEOs. Current agricultural practices have proved seriously damaging to the environment and accepting a level of harm based on this will not protect the environment. Genetic pollution should be considered undesirable because of its irreversible nature and the unpredictability of its effects. Setting a standard to protect European biodiversity by not allowing the release of GEOs which have related wild European species would be one way of doing this.

16. In the UK, one problem with the way in which the regulations are implemented is that it has proved difficult in practice for members of the public to obtain data about applications for both field trials and commercial releases. This is not simply frustrating but means important local knowledge may be lost to the evaluation process. For example, when the license was given to allow the testing of genetically modified maize in Cornwall, the advisory committee may not have realised that a neighbouring farmer’s livelihood could be

¹ This is supported by research into the regulatory system, e.g., Levidow, L (1994) *Biotechnology regulation as symbolic normalisation. Technology Analysis and Strategic management* 6: 273-288.

threatened if there was cross fertilization of his crop and the loss of his organic status. We believe that information should be available more easily and quickly to the public.

17. To do this Member State should ensure knowledge of a proposed deliberate release is made widely available. Any requests for information about a proposed deliberate release must be supplied within 10 days.

THE MOST APPROPRIATE JURISDICTION FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

18. It is crucial that both national and international regulations are in place. National scrutiny is required to ensure local knowledge is brought to bear on a decision. International regulation is required because GEOs are living organisms which will not respect national borders.

THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND COMPETITION

19. There has to be effective regulation on the release of GEOs if confidence is to be maintained in the UK's food production systems. BSE and the collapse of the British beef industry has underlined how important this is. If regulations are relaxed and shortcomings not addressed, if and when risks were to materialise farmers could be seriously damaged through a sudden loss of consumer confidence.

20. Effective regulation which accounts for the interests of farmers who do not wish to grow genetically engineered crops is also important. If cross fertilisation between genetically engineered varieties and conventional crops, a farmer may be unable to provide the demand for non GE crops and, if they are an organic farmer could undermine their whole farming system.

21. GeneWatch believes that all sectors of industry will be best served by strict regulation under the precautionary principle. Without this confidence in British food will be undermined.

4 June 1998

APPENDIX 1

COMMENTS ON THE PROPOSAL FOR A DIRECTIVE AMENDING THE COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS (90/220/EEC)

1. THE CONCEPT OF ENVIRONMENTAL HARM IN THE DIRECTIVE MUST BE ENLARGED

22. Member States have experienced considerable difficulties in reaching agreement on decisions whether to allow the marketing of genetically modified organisms (GMOs) under Part C of 90/220. Every application has been disputed and the French Government has now introduced a moratorium on the commercial use of GMOs while a public consultation takes place. This has further highlighted the problems and confusion.

23. Disagreements about the scope of the Directive are partly the cause of the problem. Some Member States (such as Denmark and Austria) consider that an evaluation of the environmental impacts of GMOs should include all possible effects, direct and indirect, as is the case with agricultural practice. Others (such as the UK) have restricted the definition of environmental harm to the immediate impacts of the GMO. For example, under the wider definition, an assessment of GM herbicide resistant crops would also include the impacts on herbicide use, ground water pollution and weed evolution. Under the narrow definition, the possibility of gene transfer and establishment of the GMO outside the agricultural environment are the main focus of the assessment.

24. However, the Commission's proposals for the principles of the environmental risk assessment (Annex II) and the information requirements (Annex IIIA/B) take a narrow view of the risks limited to the genetic modification and the release of the GMO itself.

25. *For full environmental protection, the Commission's proposal for the principles of the risk assessment (Annex II) should be amended to include all effects from the use of the GMO, including long-term effects from the use of chemicals, and take into account the availability and suitability of alternative production systems. The information requirements (Annex IIIA/B and Annex IV) should be amended accordingly.*

2. RELEASES MUST BE IN THE PUBLIC INTEREST

26. As well as the narrow scope causing problems, there are also disagreements over whether identified risks are significant or not. For example, some countries feel that the emergence of herbicide tolerance weeds should be avoided and so opposed commercial scale releases of herbicide resistant oilseed rape. Other felt the risks are tolerable and manageable with the use of different herbicides. This lack of agreement on the "so what?" question reflects the considerable scientific uncertainty about scale, extent and degree to which any risk will be experienced. Therefore the disagreements are over what is considered justifiable harm. However, neither the Deliberate Release Directive nor the Commission's proposed revision allow the debate to be articulated in honest

terms like these. Rather the emphasis is on conducting the debate in technical terminology even though this does not form the real basis of the conflict over the risks and no scientific certainty exists with which to resolve the issue.

27. The narrow, technical nature of the regulations conceals a “taken-for-granted” assumption inside the system that genetically engineered organisms represent positive progress, yet this is a view which research shows is far from widely held. Therefore, its assumption in policy is profoundly anti-democratic. Considering the physical dimensions of risk alone excludes articulation of value judgments about effects on future generations, or the morality and justification for taking any particular risk and these are of fundamental importance to evaluating risk for most people. Therefore if the Directive does not tackle this issue it will never command public confidence.

28. *GeneWatch believes the revised Directive must allow for an explicit evaluation of whether the risks of a GMO release are in the public interest.*

29. Such a public interest provision in the risk assessment would be analogous to the requirement to justify nuclear discharges and demonstrate a social benefit in the regulation of the nuclear industry, the Fourth Hurdle used to assess BST and the provisions in Norwegian Gene Technology Act. There are practical tools which could be used to help decision makers in evaluations of public interest. These include techniques such as multi-criteria evaluation, citizens’ juries and consensus conferences. An explicit public interest clause could result in decisions being more robust as they should more accurately represent public opinion.

3. MANDATORY SEGREGATION OF GMOs SHOULD FORM PART OF THE REVISED DIRECTIVE

30. The Commission’s proposed revisions include a requirement for post-marketing monitoring (Articles 15(2) and 22(2)) and a re-evaluation of the licence after a seven year period (Article 22 (3)). However, monitoring and re-evaluation cannot be considered to provide reliable safety mechanisms because they have serious limitations in practice. Firstly, deciding what to monitor, how often and where, presumes the risks are known and this is a dangerous assumption. The emerging evidence that certain chemicals cause sex changes in fish was not predicted and was discovered by chance. Unexpected impacts of GMOs may cause similar surprises. Secondly, the irreversible nature of the risks of releases of GMOs means that when harm is discovered through monitoring or by chance, it is unlikely that anything will be able to be done to rectify matters. Thirdly, the time-scale over which harm may arise may not be detected inside seven years. Damage from the introduction of exotic species to new environments can take decades to emerge. A false sense of security may be engendered if a positive seven year review is equated with safety.

31. However, as well as these basic problems with the principles of monitoring and re-evaluation as safety management tools, they will be completely unable to identify even gross harm unless mandatory segregation of GMOs is put in place. Without this, it will prove impossible to track and evaluate their effects at any stage, be it on consumers, the environment or agriculture.

32. *The proposed Directive must be amended to include the provision for mandatory segregation of GMOs and their tracking through the environment and food chain. Such a system would also allow for full labelling to take place and facilitate consumer choice.*

4. SHORTCOMINGS OF THE CASE-BY-CASE APPROACH MUST BE ADDRESSED

33. Under both the current and proposed revision to the Directive, case-by-case assessment is the only approach envisaged. By looking at each GMO in isolation, the possibility of cumulative effects is neglected. For example, many crops are being engineered to include a insecticidal toxin (*Bacillus thuringiensis* toxin in particular) so they can resist insect attack. Because the toxin is present throughout the growing cycle rather than intermittently, beneficial insects and birds which normally feed on the pest species may lose their food supply completely. When considered on a crop-by-crop basis, the likelihood of this occurring or having any serious effect may seem remote, but if the majority of crops planted carry such a toxin, there could be serious impacts on some species.

34. *The Directive should be amended to allow for the review of the potential for cumulative impacts of classes of genetic modification. This could include, for example, insect and herbicide resistance and should be undertaken before approvals for individual products are given.*

5. SIMPLIFIED PROCEDURES ARE TOO DANGEROUS TO PUT IN PLACE AT THIS TIME

35. Articles 18 and 19 of the Commission’s proposed revision contemplate the introduction of simplified procedures for the placing on the market of GMOs. The Commission or Member States can make proposals and, if accepted, would lead to a fast track approval process with much shorter times for evaluation and public scrutiny. The real danger is that the types of GMOs that would be recommended for this simplified procedure would be similar to those already approved. Whilst this sounds a sensible approach, it would mean even less attention being given to the issue of cumulative impacts (see above). There is also very limited knowledge about

the commercial use of GMOs in the European Union—to date there have been no crops grown on a commercial scale at all.

36. *Simplified procedures for the marketing of GMOs should not be allowed at this stage. Knowledge about their impacts may go undetected if fast tract approvals are allowed. Therefore, Articles 18 and 19 should be deleted.*

6. PLACING EVALUATIONS OF GMOs UNDER PRODUCT REGULATIONS WILL COMPROMISE SAFETY

37. Under Article 14 of the Commission's proposed revision, GMOs to be marketed could be assessed under product regulations. In practice this means that a GMO intended to be used as a pesticide (a virus engineered to kill insects for example) could be assessed under pesticides regulations if this included a "similar" risk assessment process to that laid down in the Directive. Although superficially this seems like streamlining, it could result in GMOs being considered by authorities ill-equipped to evaluate the risks of the genetic modification because their normal work involves the assessment of more conventional pesticides. Thus important safety considerations may be overlooked.

38. *Evaluations of GMOs must be undertaken by those with the specialised knowledge required. Article 14 of the proposed revision should be deleted to avoid the erosion of safety standards through less rigorous scrutiny by less experienced agencies.*

Liability for harm

39. To encourage companies to make a realistic assessment of the risks and to ensure that should harm arise it will not be left to public funds to pay any costs arising, a system of strict liability should be put in place.

40. *The proposed revision of 90/220 should include an article which puts in place strict liability for environmental or other harm arising from the release of a GMO.*

Memorandum by Dr Chris Gliddon, School of Biological Sciences, University of Wales

1. PREAMBLE

1.1 The following evidence relates to the problems associated with the lack of consistency of implementation and interpretation of Directive 90/220/EEC. Issues of harmonisation with the EU are addressed and suggestions for amendment of the Directive are addressed.

2. RISK

2.1 A widely accepted definition of *Risk* is a measure of the effects (economic, injury, environment) of an occurrence in terms of both its *probability* and the *magnitude* of its consequences. This simple definition immediately requires that risk be decomposable into two main components: the hazard and its likelihood.

2.2 *Hazard* can be defined as the property of a substance or a process that can cause harm. Hazard can never be zero; it can be direct or indirect, immediate or delayed, natural or technological, intentional or unintentional. *Harm* is the manifestation of that hazard. Given this, risk can be defined risk as the product of (1) the magnitude of the harm (generated by a hazard) and (2) the frequency with which the hazard occurs.

3. RISK ASSESSMENT AND RISK MANAGEMENT

3.1 Risk assessment is the scientifically based process consisting of the identification and characterisation of hazards, the assessment of exposure and the characterisation of the resulting risk. Risk management is the process of weighing policy alternatives in the light of the results of the risk assessment and if required, selecting and implementing appropriate control options including regulatory measures. That is, risk assessment seeks to identify the hazards and determines the likelihood of their occurrence, i.e., the probability of something going wrong. Risk management then can, as a result of this process, allow necessary controls to be put into place to eliminate the hazard or, if this is not possible, to reduce the risk of the hazard causing harm.

3.2 Environment risk assessment is the systematic evaluation of the risks associated with hazards to human health and safety and the environment, arising from human activities capable of impacting on the environment on a continuous or accidental basis.

4. *The process of environmental risk assessment*

4.1 The following sequence of procedures for risk assessment has been proposed:

- (i) identification of hazards;
- (ii) estimation of their magnitude;
- (iii) estimation of the frequency of their occurrence;
- (iv) evaluation of risks.

4.2 Risk assessment is feasible even in situations where current information is limited, providing its purposes and limitations are realised. Risk assessment should be an iterative process. The earliest analysis might determine where more information is needed to support credible risk assessments in future iterations and provide limited guidance in reducing risks to health and the environment through risk management and in the continuing decision-making process associated with remediation.

4.3 The way to present the results of a risk assessment in which variability and uncertainty are acknowledged is controversial. This is often as a result of confusion regarding the difference between variability and uncertainty. Variability comprises a population's natural heterogeneity or diversity, which does not change through further measurement or study, although better sampling can improve an estimate of its magnitude. Uncertainty, in contrast, reflects gaps in information about scientifically observable phenomena. Uncertainty sometimes can be reduced through further measurement or study and several quantitative methods to describe risk-assessment uncertainties are currently being explored. Although there is general agreement as to the value of qualitative statements describing critical uncertainties in health risk assessment, formal quantitative approaches to uncertainty analysis are complex, difficult to perform, difficult to understand and often unnecessary. Variability, in contrast, can be described much more readily and can be based on actual measurements.

4.4 Appropriate risk assessment consists of the application, in a systematic manner, of a wide range of scientific methods in order to master:

- (i) how information is gathered systematically;
- (ii) how its uncertainty is determined;
- (iii) how potential future outcomes and their impacts are explored in an objective and reproducible manner;
- (iv) how the likelihood of these outcomes is displayed clearly and comprehensively.

5. THE ACTUALITY OF ENVIRONMENTAL RISK ASSESSMENT

5.1 A review of the current situation regarding applications for consent to market GMO's within the EU, with almost every application eventually being referred to the Article 21 Committee, shows clearly that environmental risk assessments are not performed and/or interpreted consistently among the various Member States.

5.2 This lack of consistency seems to derive from (1) several weaknesses both in the present regulatory framework and the way it has been implemented nationally as well as from (2) significant gaps in the underlying science base.

6. THE REGULATORY FRAMEWORK

6.1 Hazards cannot be zero and, as such, there is a risk associated with every release of a GMO. In this context, the use of the products of modern biotechnology is often perceived as a possible threat. It would be useful, therefore, if both regulators and consumers were able to balance potential risk against possible benefit. The scope of Directive 90/220 is to allow the release of a GMO based on an assessment of environmental safety and it would be in the interests of both consumers and regulators to broaden this scope to permit *environmental* risk to be balanced against *environmental* benefit.

6.2 Environmental benefits can be direct or indirect and they should be assessed against direct as well as indirect environmental risks. As such, the scope of Directive 90/220 should be broadened in order to accommodate direct as well as indirect effects.

6.3 When balancing risks against benefit we must also take into account that the "currencies" applied must be identical. Furthermore, a pragmatic approach is required when taking distant indirect effects into consideration. Their consequences become weak and therefore these should not get the same level of attention as close indirect effects or as direct effects.

6.4 The regulatory framework should promote the exchange of views among experts on pertinent issues such as hazard definition in relation to crops with relevance for European biotechnology or for genes that are currently being released in experimental field trials.

6.5 These experts could form a scientific committee that proposes to the European Commission projects that are worthy of being carried out. A demanding mandate could lead to a more efficient use of the committee that is composed of the representatives of the Member States and that has been set up under Article 21 of Directive 90/220/EEC to assist the Commission.

6.6 The information requirement for Annexes II and III of Directive 90/220/EEC should be structured so that they can be directly related to the definition of the actual hazards related to the application.

6.7 Directive 90/220/EEC should take account of the difference in data requirements between an application for a deliberate field trial and an application for a marketing dossier due to differences in both scale and location. A new annex III that is specific for multi-location, large scale marketing applications should be elaborated.

6.8 Annex II and Annex III should distinguish between requirements for different groups of organisms.

6.9 Administrative provisions should be made to allow for relevant data collection. An example is to allow for a single approval system for multi-state field trials that are considered as very important prerequisites for any commercialisation stage.

7. SCIENTIFIC LACUNAE

7.1 While well over 8,000 releases of GMOs into the environment have been made world-wide, of which about 1,000 have taken place in Europe, many of these releases have been carried out with monitoring purely designed to ensure efficacy of any confinement requirements attached to the consent. As such, much scientific information of potential value for future risk assessment remains uncollected and there is a tendency to over-value the so-called familiarity with particular classes of GMOs.

7.2 Hazard identification must depend largely on the availability of high quality data. Actions resulting in increasing the availability of data or improving their quality lead ultimately to an improvement of the processes of hazard identification and of risk assessment and should be encouraged.

7.3 Expert advice should be organised at the Community level in relation to applications for consent to market.

7.4 Apart from the need for the organisation of the expert advice, hazard identification becomes a more scientific process as more data becomes available. Therefore, both the continuing generation of high quality data and its exchange on an international basis will lead ultimately to a streamlining of the hazard identification process and should be encouraged.

7.5 Data collection, data sharing and the compilation of databases that allow for the evaluation of the interaction of a GMO with a given ecosystem are generally recognised as an essential step forward. There is a need for a systematic collection and storage of a thoroughly investigated set of information so that hazard and the concomitant risk analysis can be performed on an internationally accepted basis.

7.6 Data should be obtained from the field testing of genetically modified organisms in which some of the environmental and safety concerns match those of the marketing stage. Broad geographical field testing therefore enhances European wide experience with a specific GMO. This in turn should have a positive effect on the consideration of possible hazards involved at the marketing stage and at the approval process in all Member States.

7.7 It is not possible to compile a positive list of all hazards that need to be taken into consideration in any risk assessment dossier. Some types of hazards, such as persistence of the GMO in nature might always appear in a risk assessment dossier whereas other hazards, such as the creation of new plant pests, are dossier-specific.

7.8 Hazards might be specific for a geographical location or for a given ecosystem. A product dossier, although originating from one Member State, should ideally take into consideration all possible hazards for all possible European environments.

7.9 Hazards differ when formulated by different individuals. It is extremely important to assemble a list of perceived hazards that is complete on the one hand but sufficiently restricted on the other hand.

7.10 Directive 90/220/EEC should be modified with respect to hazard definition for the commercialisation of transgenic crops. At present, only those hazards that are directly related to the protection of human health and the environment are taken into consideration. All hazards and hazard categories pertinent to commercialisation should fall within the scope of any future modifications to the Directive.

7.11 Definition and identification of hazards are based on knowledge. An appropriate framework should be constructed to permit the definition of hazards with an intellectual input that is as high as possible.

8. LIMITATIONS OF QUANTITATIVE RISK ASSESSMENT AS APPLIED TO GMOs

8.1 The traditional framework for risk assessment and management, drawn from expertise with chemical products, involves a methodological progression through a rigorous sequence of analytical steps, including hazard identification, exposure assessment and, ultimately, risk-cost benefit assessment. The bio-ecological phenomena related to environmental releases of GMOs, however, do not submit neatly to this quantitative approach, due to the complexity of the phenomena and the scarcity of relevant data.

8.2 When organisms are released into an ecosystem, it must be realised that the various pathways of outcomes and consequences are far too numerous for detailed empirical investigations. Scientists must rely on a judgmental analysis and on reasoning by analogy.

8.3 Environmental risk assessment is still far from providing a standardised methodology that is based on data on occurrence probabilities and data from tests on effects of this release.

8.4 High quality review and test data provide the basis for decision making. Data should be collected/generated such that they can be interpreted and in a hazard-oriented model.

8.5 Experience should be fully appreciated in the risk assessment process and, for those areas where experience is lacking, experts should clearly define the need for generating research data.

8.6 The responsibility for evaluating an environmental release must thus invoke a considerable degree of scientific knowledge and qualitative judgment in order to anticipate potential harmful consequences and to balance it against the available alternatives.

Memorandum by Professor Barrie Gunter, Department of Journalism Studies, University of Sheffield

INTRODUCTION

1. The evidence provided in this submission will focus specifically on research conducted into public understanding and perceptions of biotechnology. It derives from a study conducted by the University of Sheffield (Department of Journalism Studies and Sheffield Institute for Biotechnological Law and Ethics (SIBLE)) which was funded by the Ministry of Agriculture, Fisheries and Food (MAFF).

2. The research was undertaken over a 12-month period (1 April 1997 to 31 March 1998) in four stages: (1) focus group interviews with 48 members of the public, recruited from the north and south of England; (2) a nation-wide survey of 2,185 respondents recruited across England, Scotland and Wales, interviewed face-to-face in their own homes; (3) focus group interviews with 48 teenagers (aged 16 to 19 years) recruited from the north and south of England; and a survey of 30 scientists and 31 journalists.

3. Among members of the public, this research was concerned with assessing awareness, understanding, beliefs and perceptions, attitudes and behavioural orientations in regard to biotechnology and its application in the sphere of food production. Awareness referred to the salience of biotechnology-related issues and developments in the collective public consciousness. Understanding referred to how much factual knowledge people held about biotechnology. Beliefs and perceptions focused upon sets of judgments about the truth or falsehood of different claims about biotechnology, with special regard to perceptions of the relative benefits or risks associated with it in its various forms. Attitudes embodied a more evaluative dimension in the public's appraisal of biotechnology. The question here was not one of whether biotechnology is safe or harmful (a belief) but whether it is good or bad, right or wrong, acceptable or unacceptable as an activity. At this level of analysis, the enquiry entered into the realm of the ethics of biotechnology. Behavioural orientations referred to the likelihood that a consumer would engage in a particular behaviour, such as the consumption of foods knowing that biotechnology has been involved in their production.

4. A decision was taken to survey scientists and journalists because of the significant role both of these groups play in the production and dissemination of scientific discoveries and applications of biotechnology. The sample of scientists were all currently active biotechnologists working either in the academic or commercial sectors. The journalists were recruited equally from broadcasting and the print sectors and were all known to have written or presented stories about biotechnology over the preceding 12 months. In addition to being asked questions concerning their personal beliefs and opinions regarding biotechnology (e.g., its relative risks and benefits), these two samples were asked for their views about the extent of public knowledge and understanding, the significance of the mass media in relation to the public's understanding of this branch of scientific enquiry, and the roles and responsibilities of journalists and scientists in the communication of accurate and digestible information about biotechnology.

PUBLIC AWARENESS AND UNDERSTANDING

5. A series of open-ended and pre-structured questions were administered to members of the public to assess their general awareness and knowledge about biotechnology. Preceding questions which asked directly about biotechnology in both the adult focus groups and main public survey were a number of questions concerned

with food consumption habits, diet and nutrition, and farming which provided a wider context in which to consider public awareness of biotechnology. Such questions provided an opportunity to see to what extent biotechnology and related concepts such as genetic modification were mentioned even when not directly prompted.

Perceived Changes in Diet and Farming

6. Asked about whether their personal eating habits had changed in the past 10 years, more than 70 per cent of survey respondents indicated that they had. The most commonly mentioned changes were a reduction in eating fats and fatty foods (34 per cent), red meats (22 per cent), and sugars (22 per cent) and increased consumption of fruits and vegetables (13 per cent). No mention was made of biotechnology in this context.

7. In relation to food production, most respondents (71 per cent) were able to identify changes in farming practices in the past 10 years. Among the changes mentioned most often were the perceived increase in use of pesticides, fungicides and chemicals (24 per cent), as well as the growth of technology in farming (20 per cent). It was in this context that the first unprompted mention of biotechnology occurred, with a small proportion of respondents (3 per cent) making mentions of genetic engineering, cloning and more especially, Dolly the sheep.

Awareness of Biotechnology

8. On turning their attention to biotechnology, more than half the respondents in the main survey (55 per cent) and a similar proportion in the focus groups exhibited some general awareness of the term "biotechnology". Further probing, however, revealed few respondents with any clear understanding of what this branch of science is about.

9. Upon being given more specific prompts, survey respondents most often associated biotechnology with such activities as the use of pesticides in farming (30 per cent), cloning (26 per cent), genetic modification (especially with bacteria) (24 per cent), and applying preservatives to food (23 per cent). Wider connotations emerged upon discussing the subject further in the focus groups which included the notion that biotechnology involved tampering with nature, an activity which was regarded as potentially risky and fraught with ethical problems.

Awareness of Biotechnology Regulation

10. Current public opinion in Britain sides more with the view that there is insufficient or inadequate regulation of biotechnology. More than one in two survey respondents (55 per cent) thought there was too little regulation. The responsibility for regulation of this area of science was most often spontaneously perceived to reside with the "government" (54 per cent) with more specific mentions being made by some respondents of MAFF (23 per cent), or the Department of Health (13 per cent). With prompting, one in three respondents (34 per cent) endorsed the MAFF as the primary regulator, while nearly one in four (23 per cent) chose the Department of Health.

11. There was indications from the focus groups that biotechnology awareness for many respondents was stimulated by media coverage of stories about cloning and genetic modification experiments. There was a degree of confusion over the range of events which were connected with biotechnology, as some respondents referred to issues such as *E. coli* and thalidomide as exemplars of biotechnology-related phenomena.

12. Overall, the findings indicated that public understanding of biotechnology is not very sophisticated. Respondents' uncertainty over what biotechnology entails may contribute in turn to anxieties about its implications for their own lives, especially where it represents a process which is increasingly involved in food production. There is a need to improve the general level of public knowledge and understanding of biotechnology, its implications and the way it is currently controlled and regulated.

PERCEIVED RISKS, CONCERNS AND ORIENTATIONS

13. Public perceptions of risk associated with biotechnology, concerns about various biotechnology applications, and orientations towards the use of genetically modified or otherwise biotechnologically-influenced foods were examined in the main survey and adult focus groups. At the outset of each interview, respondents in the main survey exhibited balanced views on the risks connected with biotechnology in general (33 per cent perceived more risks; 30 per cent perceived more benefits), but after further questions about the risks associated with specific biotechnology applications had been asked, the overall opinion about biotechnology shifted towards a position where risks were seen to outweigh benefits (42 per cent perceived more risks; 32 per cent perceived more benefits).

Benefits and risks associated with genetic modification and cloning

14. Turning to specific biotechnology processes or applications, members of the public were found to associate greater risk than benefit with the genetic modification of plant life where such plant life comprises crops in the human food chain, but identified net benefits for the application of genetic modification to garden

flowers and shrubs which do not normally form part of the food chain. With genetic modification of garden flowers and shrubs, the prevalence of perceived benefits (50 per cent) was far in excess of the prevalence of perceived risks (28 per cent). This pattern was reversed in the case of opinions about risks and benefits associated with genetic modification of crops for animals feeds (52 per cent risks versus 29 benefits) and the genetic modification of crops for human consumption (58 per cent risks versus 25 per cent benefits). The more direct the connection between the human food chain and genetically modified crops, the greater was the perceived overall risk. Respondents were generally of the opinion that the genetic modification of animals was a risky pursuit.

15. Risk perceptions also clearly outnumbered benefit perceptions in the case of the genetic modification of animals (66 per cent versus 15 per cent), simple organisms such as bacteria and viruses (48 per cent versus 32 per cent), and farm animals such as cows, sheep or pigs (67 per cent versus 15 per cent).

16. The cloning of animals was regarded as the most risky pursuit of all, with well over half of all survey respondents (57 per cent) saying that risks outweighed benefits. The responses of focus group participants reinforced the survey findings. Respondents continued to express the view that many genetic modification and cloning applications carried net risks.

Risk perceptions for other biological processes

17. Respondents were equally concerned about other non-biotechnology biological processes, such as the use of pesticides, antibiotics and steroids in farming, and the irradiation of food products. Clear majorities of survey respondents perceived risks to outweigh benefits in the case of pesticides (61 per cent versus 25 per cent), steroids (60 per cent versus 23 per cent) and irradiation of foods (71 per cent versus 13 per cent). Only in the case of antibiotics in farming were risk and benefit perceptions more evenly matched (44 per cent versus 40 per cent).

Images and Concerns

18. Concerns about biotechnology, whether in the form of the genetic modification of plants or animals or in the form of cloning of animals, seemed to stem from perceptions that it represented the tampering with nature and was therefore potentially dangerous or harmful. Clear majorities of main survey respondents regarded the genetic modification of crops (52 per cent) or animals (66 per cent), and the cloning of animals (80 per cent) as interference with nature. There were also question-marks over the ethics of such research and the ability of authorities to regulate it effectively. While a clear majority of respondents (70 per cent) regard cloning of animals as ethically or morally wrong, this opinion was less widely held about the genetic modification of crops (29 per cent) or animals (51 per cent). The genetic modification of crops was less often seen as impossible to regulate (29 per cent) than either the genetic modification of animals (42 per cent) or cloning of animals (48 per cent). Thus, although some respondents regarded these examples of biotechnology as inevitable (24 per cent to 30 per cent) and as representing progress (20 per cent to 30 per cent), many others felt it should either be restricted or banned, and were not willing to consider buying food derived from such processes. Banning was more closely associated with cloning (65 per cent) than either the genetic modification of animals (46 per cent) or of crops (27 per cent). Rejection of foods derived from these technologies was again more widespread in the case of cloning (48 per cent) or genetic modification of animals (42 per cent) than for the genetic modification of crops (29 per cent).

19. Other biological processes such as the use of steroids and pesticides in farming and the irradiation of food were regarded as tampering with nature (35 per cent to 48 per cent), worrying (33 per cent to 51 per cent), dangerous (26 per cent to 54 per cent) and harmful (29 per cent to 49 per cent) by many respondents. While a substantial minority also felt that the application of such processes was inevitable (22 per cent to 34 per cent), relatively few regarded it as progress (14 per cent to 27 per cent).

20. Concerns about biotechnology varied with the type of application, however. There was great deal of concern about cloning of humans (85 per cent), and the use of genetic modification on farm animals (79 per cent), other animals (such as monkeys) (74 per cent), and even upon simple organisms such as bacteria and viruses (73 per cent). There was much less widespread concern about the application of genetic modification on crops destined for animal consumption (57 per cent were concerned a great deal). Only in the case of garden flowers and shrubs were respondents generally unconcerned (just 21 per cent concerned a great deal).

Justifications for Biotechnology

21. In considering the reasons for biotechnology, respondents felt that the strongest justifications were those related to medical applications such as understanding how diseases work (76 per cent), diagnosing and treating disease and illness (69 per cent) or environmental applications aimed at reducing pollution levels (71 per cent). Food-related applications such as increasing crop yields (54 per cent saying this was a strong reason for biotechnology) or producing pesticide resistant crops (60 per cent) were less widely supported. An application

such as making farm animals grow larger or faster (15 per cent) and pure research in biotechnology to create new animal species (13 per cent) were much less widely supported.

Opinions about Genetically Modified Foods

22. Looking further into opinions about genetically modified foods, respondents continued to express doubts and concerns, but also indicated very clearly that they needed more information about such products and the scientific processes underpinning them (70 per cent expressed this need). Deep-seated suspicion about genetic modification and other forms of biotechnology when applied to food production were also revealed in the cautious or negative orientations observed towards such food. A majority of survey respondents not only roundly rejected meat derived from genetically modified animals (60 per cent), but also meat from ordinary animals fed on genetically modified crops (53 per cent). Even with government or manufacturer reassurances and endorsements, many respondents remained uncertain and unconvinced about such foods. Fewer than one in three respondents said they would buy genetically modified foods endorsed as safe by government (31 per cent) or by manufacturers (32 per cent). Most respondents indicated an unwillingness to buy foods from crops sprayed with pesticides (53 per cent) and tended increasingly to purchase food products where all ingredients were clearly shown on the packaging (53 per cent).

23. The net outcome of this part of the research was that members of the public expressed considerable concerns and reservations about biotechnology and especially about the derivation of foods from genetically modified plant and animal life forms. They perceived such products and the processes which underpin them as carrying more risks than benefits, as problematic, as unnatural and perhaps also unethical, and as something, for the time being at least, to be avoided. Although certain sections of the population (e.g., the young) were more inclined than others to give genetically modified foods the benefit of the doubt, there remains a considerable amount of successful persuasion to be done to create general public support for and likely consumption of genetically modified foods.

INFORMATION SOURCES AND BIOTECHNOLOGY

24. Respondents in the main survey were questioned about their media consumption patterns, especially their consumption of specialist media output, such as magazines, radio and television broadcasts which dealt with subjects of potential relevance to biotechnology awareness. They were also asked more directly about their main sources of information concerning biotechnology.

Biotechnology Information Sources

25. The sources which received the most mentions were television news and documentaries (58 per cent), newspapers or news magazines (47 per cent), consumer programmes on television (24 per cent), and talking to other people (17 per cent). Radio broadcasts of any kind were identified far less frequently (by 6 per cent or fewer respondents) as information sources of significance in this context. Primary information sources did vary in certain ways between subgroups within the sample. Teenage respondents (29 per cent), for example, mentioned studying science at school or college as being among the most important sources of information about biotechnology far more often than did older age groups. There were a few mentions, by minorities of respondents, of government-released information and labels on food products.

26. Respondents were also asked which information sources they would mistrust. Sources mentioned most often as being potentially unreliable were newspapers (23 per cent), government (22 per cent), other people (20 per cent), and food manufacturers (20 per cent). Food retailers (15 per cent) and food labels (11 per cent) were the next most often mentioned after the aforementioned. It is clear then that official sources do not hold the public's trust. Among the mass media, the broadcast media were generally regarded as more reliable than print media. Despite the relatively high rank achieved by supermarkets and food retailers in the league table of mistrusted information sources, most respondents (59 per cent) nevertheless acknowledged picking up and taking away information leaflets provided by supermarkets. A substantial minority of respondents (44 per cent) also expressed at least some interest in watching in-store videos with food-related information and others (54 per cent of VCR owners) said they would be prepared to take such videos home with them to watch provided they were available for free. The popularity of the latter idea dropped dramatically with the suggestion that a £5 charge would be levied for such videos (13 per cent expressed some interest on this basis).

Media habits and Biotechnology Awareness and Opinions

27. Although the results reported in this research cannot prove cause-effect relationships between media exposure and biotechnology-related awareness, attitudes, perceptions and orientation, they do reveal that different amounts and types of media consumption differentiate levels of public biotechnology knowledge and the kinds of opinions held about biotechnology. At a very basic level, awareness of biotechnology was greater among respondents who were regular than irregular consumers of the major print and broadcast media.

28. Broadsheet newspaper readers (85 per cent) were more likely to have heard of biotechnology than tabloid readers (52 per cent). Respondents who reportedly read, listened to or viewed specialist magazines (66 per cent), radio (73 per cent) or television broadcasts (59 per cent) were more likely than non-consumers of these programmes (51 per cent, 52 per cent and 59 per cent respectively) to say they had heard of biotechnology.

29. These differences in reported media consumption also distinguished respondents in terms of their awareness of biotechnology regulation as well. Broadsheet readers were more likely than tabloid readers to say there was far too little regulation of biotechnology (37 per cent versus 26 per cent). This opinion was also more likely to be expressed by specialist magazine readers than non-readers (34 per cent versus 26 per cent), special interest radio programme listeners than non-listeners (40 per cent versus 26 per cent), and special interest television programme viewers than non-viewers (31 per cent versus 19 per cent). In other words, people who regularly tune in to the major news media and more particularly those who make a point of consuming special interest publications and productions are more informed and more opinionated.

SURVEY OF SCIENTISTS AND JOURNALISTS

30. The main aims of this survey were:

- (1) to find out if the perceptions of biotechnology risks and benefits, and other opinions about different biotechnology applications were similar among these two specialist groups as they had been found to be among members of the public;
- (2) to ascertain journalists' and scientists' perceptions of the public's need to know about and their current level of understanding about biotechnology;
- (3) to examine journalists' and scientists' perceptions of the role of the media in enhancing public understanding and opinion about biotechnology; and
- (4) to explore scientists' and journalists' perceptions of their own respective roles and responsibilities in relation to helping members of the public understand what they need and ought to know about different applications of biotechnology.

Perceptions of Benefits and Risks

31. Scientists and journalists were much more confident than the public about the risks and benefits associated with biotechnology. An overwhelming majority of the scientists (93 per cent) interviewed in this survey and a clear majority of the journalists (65 per cent) interviewed here, believed that benefits outweighed risks. The public had been found to be much more circumspect in their opinions and consequently were less convinced about the benefits and absence of serious risks.

Perceptions of Public Knowledge and Opinion

32. Scientists and journalists showed general agreement about the public's need to know more about biotechnology, especially in the context of food production. A majority of both groups also believed that only a small minority (less than 20 per cent) of the public had any real knowledge of biotechnology (journalists–71 per cent; scientists–80 per cent) or genetic modification (journalists–67 per cent; scientists–80 per cent).

33. If the public were largely ignorant, what role if any could the media play in alleviating this position? When asked to judge the quality of media coverage of biotechnology issues, scientists revealed a series of largely negative opinions. Media coverage of biotechnology and genetic modification in general, for example, was regarded as too sensational and dramatic (journalists–58 per cent; scientists–83 per cent), too speculative (45 per cent and 73 per cent) with too much emphasis on risks (45 per cent and 63 per cent), and as failing in its scientific accuracy (42 per cent and 20 per cent) and balance (39 per cent and 10 per cent). Journalists, not too surprisingly, held a different and somewhat more positive set of opinions. Even so, many of the journalists interviewed shared the scientists' reservations about media coverage of biotechnology. Thus, even media professionals were inclined to question the quality of treatment accorded to this complex subject by the major news media.

Principle Functions of Journalism

34. Given that there was a broad implication from these opinions that media coverage could be better, whose responsibility is it to ensure that improvements occur? Both groups were asked to consider, in particular, the functions of journalism in regard to reporting of science and biotechnology. Spontaneous and prompted opinions were sought. In both instances, there was widespread agreement that journalism had a duty to inform the public and to do so objectively. Both journalists and scientists widely and spontaneously mentioned the need for objectivity in reporting on scientific matters (71 per cent and 67 per cent). While it was generally agreed spontaneously that there was little room for undue emotion in reporting on science and biotechnology

(journalists—39 per cent; scientists—47 per cent), it was also, with prompting, seen as important to use reporting techniques which would make the subject matter interesting (journalists—97 per cent; scientists—80 per cent) and comprehensible to non-experts (journalists—97 per cent; scientists—97 per cent).

Interactions between Scientists and Journalists

35. Journalists (94 per cent) and scientists (93 per cent) both overwhelming agreed that journalists should be technically prepared before interviewing scientists. Journalists should not enter into an interview with a scientist on a technical subject without having first done some homework and attained a degree of understanding on their own part. This opinion would seem to fit sensibly with the further opinion, widely endorsed by scientists and journalists, that part of the journalist's task, was to translate complex science into everyday language (journalists—97 per cent; scientists—80 per cent).

36. A majority of both groups also believed that scientists should restrict themselves to statements about their field of expertise and not wander into territory where they are less sure of themselves (journalists—58 per cent; scientists—73 per cent). In addition, both groups agreed that journalists should not accept the word of scientists at face value (journalists—58 per cent; scientists—70 per cent). The implication of this opinion is that journalists have a professional duty to check the facts at their disposal and to verify any statements they might quote even though these may have been obtained from scientific "experts". However, a possibly complicating factor in this respect was that journalists were much keener than were scientists for science experts to venture opinions in addition to simply stating facts (61 per cent versus 43 per cent). Where scientists and journalists seriously disagreed was on the right of scientists to check a journalist's copy before publication. Nearly every scientist (93 per cent) interviewed wanted to be able to do this, while three out of four journalists (74 per cent) voiced outright rejection of such an idea.

The Role of Scientists

37. It was argued that scientists have a role to play in the enhancement of public understanding of science as well as journalists. In this regard scientists and journalists appeared to be of one mind. The great majority of those interviewed in this survey agreed that scientists had such a role (journalists—97 per cent; scientists—97 per cent) and need to make more effort to fulfil it (94 per cent and 97 per cent). Both groups readily acknowledged that scientists often distrust journalists (71 per cent and 90 per cent) and suffer also for a lack of training and ability in communicating their findings in lay terms to the general public (journalists—71 per cent; scientists—73 per cent). Most specialist respondents agreed that scientists need more training in communications skills (journalists—87 per cent; scientists—97 per cent).

38. The only respect in which journalists and scientists differed in their viewpoint was that two-thirds of scientists (67 per cent), as compared with one-third of journalists (35 per cent) who were interviewed, recognised that getting their research into the news is not important for most scientists. This opinion, among the scientists, is undoubtedly conditioned by the need, in the case of many of them, to publish academic papers as a primary aspect of gaining professional recognition and career advancement. The solution to this problem lies in a change of attitude among scientific researchers in the value attached to non-academic and non-technical as well as academic and technical forms of publication of scientific research findings. Scientists need not only the training, but also the incentives to commit themselves to "going public" on their research in a wider sense than airing the results of their endeavours in publications only likely to be read by their professional peers.

28 May 1998

Memorandum by the Health and Safety Executive

BACKGROUND

Health and Safety Commission and Health and Safety Executive

1. The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) are both statutory non-departmental public bodies. The HSC's 10 members are appointed by the Secretary of State for the Environment, Transport and the Regions after consultation with organisations representing employers, employees, local authorities and others as appropriate. The HSC's statutory responsibilities under the Health and Safety at Work, etc. Act 1974 include proposing health and safety regulations and standards to Ministers. The Health and Safety Executive is a body of three people appointed by the HSC with the consent of the Secretary of State for the Environment, Transport and the Regions. The Executive is supported by about 4,000 staff (HSE), including inspectors, policy advisors, and scientific, technological and medical experts. Of these some 350 are in the Health and Safety Laboratory, an in-house Agency of HSE.

2. The HSC relies on the policy advice of HSE, and also advice from a wide variety of interests including trade unions, employers' organisations and scientific and technological experts. Much of this advice is managed

through a network of advisory committees. Some of these deal with particular hazard areas and some with particular industries. Each includes a balance of employer and employee representatives and, where appropriate, technological and professional experts. Their main function is to recommend standards and guidance on health and safety matters to HSC. Advisory committees are serviced by HSE.

Advisory Committee on Genetic Modification

3. The Advisory Committee on Genetic Modification (ACGM) is one of HSC's subject advisory committees and was established in 1984. Its original remit was to advise the HSC/E and interested Ministers on all aspects of work with genetically modified organisms (GMOs). After the Advisory Committee on Releases into the Environment (ACRE) was established to advise the Secretary of State and HSC/E on aspects of human and environmental safety of the release of GMOs and other novel organisms into the environment, ACGM confined itself to GMO activities under conditions of containment (e.g., work in laboratories and industrial installations). ACGM's remit is to advise on any aspect of contained use. Since 1993 this has included the Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996.

4. ACGM comprises 13 members appointed by HSC. This includes a chairman who is an independent expert; four nominees of employers' organisations; and four nominees of employees' organisations; and four independent experts of whom one must specialise in environmental safety. The current chairman is Professor Kay Davies, CBE, of Oxford University. ACGM has a Technical Sub-Committee comprising a chairman and 12 members (representing an appropriate balance of expertise and employer and employee interests) who provide specialised technical advice in all aspects of the human and environmental safety of the contained use of GMOs. ACGM's focus is on safety aspects of genetic modification; it does not consider social or ethical aspects. It is also not involved in consideration of product safety which is handled under deliberate release or product based legislation.

REGULATORY CONTROL OF GENETIC MODIFICATION

5. Regulations to control the safety of genetic modification (GM) work have been in place in Great Britain (GB) since 1978. In 1989 the Regulations were extended to cover experimental releases of GMOs into the environment, though the purpose of the legislation was restricted to the protection of human health. Specific provision for environmental safety of GMOs was addressed in Part VI of the Environmental Protection Act 1990¹ (EPA). At the same time there were moves in the European Community to establish common human health and environmental standards for all GM work including the marketing of GM products. These standards are specified in two Directives which were adopted in 1990. They deal respectively with the contained use of genetically modified micro-organisms (GMMs) (90/219/EEC)² and the deliberate release into the environment of GMOs (90/220/EEC)³. ACGM's interests do not extend to Directive 90/220/EEC.

Legislation on contained use of genetically modified organisms

6. "Contained Use" means any operation in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers with chemical or biological barriers or both, are used to limit their contact with people and the environment. This definition covers activities such as laboratory operations, housing and breeding of GM animals in animal houses or farm animals restrained by fencing, the use of growth rooms and glasshouses, and the use of fermenters.

7. The Contained Use Directive is implemented in Great Britain through regulations made under the powers of the Health and Safety at Work, etc., Act 1974, and the European Communities Act 1972. The regulations are concerned with protecting both human health and the environment. They comprise the Genetically Modified Organisms (Contained Use) Regulations 1992⁴ and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996⁵. They require, with certain exceptions, that anyone carrying out any activity involving genetic modification does so in conditions of contained use which satisfy the Regulations. All contained use activities must be risk-assessed, and containment and control measures must be applied. The Regulations require notification in advance to HSE before any premises are used for GM activities for the first time. Where higher risk GMOs are involved individual activities must also be notified to HSE. In some cases a specific consent from HSE is required before the work can begin. HSE may only grant such a consent with the agreement of the SoS.

8. The information given in notifications assists HSE and other government departments to ensure that GMOs are being properly assessed and handled under the correct conditions. To do this, HSE consults with

¹ (1990 C.43).

² (OJ No. L 117, 8 May 1990, p. 1).

³ (OJ No. L 117, 8 May 1990, p. 15).

⁴ (SI 1992/3217).

⁵ (SI 1996/967).

Department of Environment, Transport and the Regions (DETR), Ministry of Agriculture Fisheries and Food (MAFF), Scottish Office and Welsh Office; together these organisations evaluate the notification in terms of human health and environmental safety. HSE may also seek the advice of ACGM.

9. The Contained Use *Directive* covers only genetically modified micro-organisms (GMMs). However, the GB legislation which implements the Directive also covers GM animals and plants insofar as they may present risks to human health. For GMMs the Regulations cover both human health and environmental risks. The environmental risks associated with work with larger organisms (GMOs) are covered separately by section 108(1)(a) of the EPA. This section requires anyone acquiring a GMO which is not an approved product under the Genetically Modified Organisms (Deliberate Release) Regulations 1991 to carry out a risk assessment of the environmental risks.

10. The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996¹ require records on the risk assessment to be kept for 10 years. These were amended by the Genetically Modified Organism (Deliberate Release and Risk Assessment—Amendment) Regulations 1997.²

Proposed amendment to Contained Use Directive (90/219/EEC)

11. A proposal for fundamental revision of the Contained Use Directive (90/219/EEC) has been under negotiation in the European Council of Ministers since May 1996. The initiative began with a 1993 House of Lords Select Committee on Science and Technology,³ and a European Commission White Paper⁴ on competitiveness suggesting a review of the biotechnology regulatory framework in order to simplify it. It was also necessary to match controls more scientifically to the kind of GMO activities now carried out and to what is known about the risks.

12. The proposed revision streamlines administrative procedures and places greater emphasis on risk assessment and containment and control measures. It is currently at Second Reading stage in the European Parliament, and it is hoped to achieve final adoption by about September 1998. Implementation in Great Britain is likely to be in March/April 2000.

Operation of the GB contained use legislation

13. The HSE and the Secretary of State are joint competent authorities (HSE is given the decision-making power, but cannot act on environmental issues without the agreement of the Secretary of State). HSE receives all notifications and other information submitted under the legislation. Under a Memorandum of Understanding all of this information is circulated to DETR, MAFF, Scottish Office and Welsh Office for their comment. This system works very well and allows HSE to draw on the experience and knowledge of other Government Departments as well as ACGM's advice when appropriate.

Enforcement of the contained use legislation

14. The contained use legislation is enforced by HSE specialist inspectors. In enforcing *environmental* aspects of GM animals and plants controlled under Part VI of the EPA and associated regulations, HSE operates under an Agency Agreement with DETR.

Relevance of contained use legislation to genetic modification in agriculture

15. Research and development leading to agricultural products is a step-wise process. It will typically form a continuum from laboratory-based studies, to growthrooms and glasshouses, to small-scale field trials, and finally to commercialisation. The initial (contained) stages are controlled under the contained use legislation. The sorts of studies include initial insertion of new genes into plants, creation of animal embryos with new genes, development and production of novel veterinary medicines and growth studies in glasshouses. Field trials and production involving deliberate release, and product approval do not fall under the contained use legislation. DETR lead on matters concerning deliberate release of GMOs under the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended in 1995 and 1997). MAFF have responsibility for all aspects of the use of GM technology for the production of foods under the Novel Foods and Novel Food Ingredients Regulations 1997.⁵

29 May 1998

¹ (SI 1996/1106).

² (SI 1997/1900).

³ (Regulation of the UK Biotechnology Industry and Global Competitiveness; HL Paper 80).

⁴ (X1/506/94).

⁵ OJ No. L43 14 February 1997 pl.

APPENDIX

INFORMATION SUPPLIED AT THE REQUEST OF THE COMMITTEE ON THE MODIFICATION OF SALMON

1. A Scottish Company, Otter Ferry Salmon Ltd, notified the Health and Safety Executive on 20 December 1995 of their intention to undertake genetic modification of the Atlantic salmon. They were proposing to produce transgenic Atlantic Salmon carrying extra copies of the Chinook Salmon growth hormone gene, linked to the "anti-freeze" protein gene promoter from the Ocean Pout. The Atlantic Pout is a member of the Cod family, and is able to survive extreme cold that would kill salmon.

2. The Company were intending to evaluate technology developed in Canada, primarily to develop methods to protect farmed Salmon from freezing during severe cold weather. The strategy involved the insertion of an "anti-freeze" gene, which would produce a protein which would protect the fish from freezing. A growth hormone gene was also attached to the anti-freeze gene, in an attempt to accelerate growth. The experiment was successful in initial laboratory trials, but was apparently blocked by the Canadian authorities, due to concerns about environmental safety.

3. These concerns centred on the ability of any escaped salmon to move to waters normally too cold for survival, hence opening up new habitats. Furthermore, the fish could grow to a very large size—in initial experiments the salmon grew at up to 22 times normal rate, with 10 times being average.

4. Following the success of the early work, the scientists removed the anti-freeze gene, and concentrated on the potential for accelerated growth. They contacted Otter Ferry Salmon Ltd., with a view to evaluating the technology on a commercial fish farm. Otter Ferry were identified because they are land based, and do not use sea cages. However, they are located on the shore of Loch Fyne, which is a habitat for wild Atlantic Salmon.

5. Following the initial notification to HSE, concerns were raised over the potential environmental impact in the event of an accidental release of the transgenic fish, and a site inspection was arranged to assess the standard of containment, and evaluate the likely degree of control. The site was visited on 2 February 1995, as part of my section's primary inspection programme. As the concerns being raised were entirely environmental, I invited Dr Monroe from the Scottish Office marine laboratory in Aberdeen, to accompany me.

6. I made a series of recommendations to the Company, relating to physical containment and management procedures, incorporating advice from fish farming experts in Scottish Office and MAFF, as well as advice from DOE (DETR). The company indicated that it would be able to comply with the recommendations, and that no work would start until HSE was satisfied with the facility.

7. A clearance letter under the Genetically Modified Organisms (Contained Use) Regulations 1992, was issued to Otter Ferry on 17 March, indicating that HSE had no objections to work commencing on human health and safety grounds, but reminding the company that there were outstanding environmental issues to be resolved. Work with salmon is seasonal, and the notifiers indicated that they wished to start in November/December 1995.

8. Otter Ferry contacted HSE in April 1995 to confirm that the recommendations had been met, and a second visit was arranged for 30 May. An old "wet laboratory" had been converted into the containment unit, and whilst the standard of containment was considerably higher than the original facility, a number of further recommendations were made.

9. These were complied with, and a final check visit was arranged for 6 October. During the visit I was again accompanied by Dr Monroe (Scottish Office). A full inspection was carried out, and included testing of alarm systems and back-up procedures. A number of refinements to the system were suggested, and these were agreed by the company. A letter containing the recommendations, was sent to Otter Ferry on 13 October. This letter indicated that HSE, acting on behalf of Scottish Office and DOE, had no objections to work commencing, assuming the standards of containment were maintained, and management control was adequate to ensure long term containment.

10. Work commenced in January 1996, with scientists from Canada coming over to carry out the micro-injection of the fish eggs. The results were not as good as hoped, and some 150 "transgenics" were identified from 10,000 eggs injected. These showed considerably increased growth, although the work was not carried out in a scientific manner, and all the non-transgenic "controls" were destroyed, making meaningful comparisons impossible.

11. The company was visited again to ensure that work procedures and management controls were being maintained. Standards on subsequent visits were good. During these visits, the Company indicated that they were looking for someone else to take the work on, as it was not central to their business aims. Furthermore,

publicity about the work, both in the UK and Europe was damaging their reputation. They were unable to find anyone willing to take over the project, and the transgenics were destroyed. No further work is planned.

12. If you require further briefing papers, please do not hesitate to contact me.

Dr Paul Logan

Directorate of Science and Technology

Biotechnology Section

5 June 1998

Background notes

(i) All organisations wishing to undertake research involving genetic modification under contained conditions for the first time, have to notify HSE 90 days in advance under the Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996. Unless HSE objects work can commence after the 90 day period. HSE usually sends a "clearance letter" to the notifier, however, this is not a consent or licence. This legislation covers both human health and environmental safety in relation to genetically modified micro-organisms, and human health aspects of work involving genetically modified animals and plants. Environmental safety aspects of the work is covered by the Genetically Modified Organisms (Risk assessment) (Records and exemptions) Regulations 1996, which implemented Section 108(1) of the Environmental Protection Act 1990.

(ii) HSE undertakes inspections of facilities used for the containment of transgenic animals and plants under a Departmental arrangement with DETR, who have the lead in relation to environmental safety aspects of genetic modification work in England and Wales. DETR advise the Scottish Office on these environmental safety issues.

(iii) HSE specialist inspectors carry warrants issued under the Environment Protection Act 1990. They have the power to issue a prohibition notice if work activities could lead to harm to the environment, or to prosecute in serious cases.

(iv) Initial Inspection of the facilities that were notified as the "Containment area" revealed that the standard of containment was poor, and there was a significant risk of accidental release. Following the inspection it was made clear to the Company that I did not consider that the containment measures were adequate to ensure that genetically modified fish could not enter the environment. It was made clear that work should not proceed unless the facilities were appropriate to ensure that the genetically modified fish could not enter into the environment.

Memorandum by Horticulture Research International

CONTEXT: HRI'S PERSPECTIVE

1. Horticulture Research International (HRI) is a Public Sector Research Establishment (PSRE) with the principal objective of carrying out horticultural research and development. It is the principal contractor for horticultural R&D in the UK and is recognised as a centre of excellence providing cost-effective R&D. HRI has a significant research effort in genetic modification which is used in two distinct ways. The first as a research tool to identify gene properties and functions and the second is to produce improved cultivars by incorporating specific genes through genetic engineering. Targets are primarily fruit and vegetables for fresh consumption or processing and ornamental species for amenity and leisure purposes.

2. *Containment (90/219/EEC)*. HRI has carried out basic research involving genetic modification for over 10 years, including the first transformations of apple and strawberry. Most of the current work is carried out under the provisions of 90/219/EEC. This has provided a safe, effective framework for contained research. Risk assessments use well-established methods and information, which has proved to be robust. The assessments and supporting practical protocols protect operators from potential risks and avoid harm to the environment.

3. *Release (90/220/EEC)*. The release of GMOs arising from HRI R&D into the environment is so far limited to studies on long term stability of transgenes in Apple. The application procedure for consent for release of GMOs for experimental purposes requires comprehensive details on the transgenic organism and a detailed assessment of the risk of harm to human health and the environment. Where consent has been given and the trials carried out in accordance with the protocols detailed in the application, the system has been successful in allowing experiments to proceed without adverse consequences. The system is open and releases are publicised. This has led to problems such as vandalism and attacks on GMOs. There is thus currently a conflict between the need for transparency in GMO trialling, essential to retain public confidence, and the need to maintain security of the trials.

4. Consent for Marketing under this directive requires the agreement of all 15 member states of the EU and is consequently a major barrier to GMOs reaching the marketplace. This is in contrast with the relatively streamlined system for consent in the USA. While protecting the rights of individual states is a political necessity, it is important that agreement for non-controversial GMOs does not place European firms and their products at a competitive global disadvantage.

5. Novel Foods (EC) 258/97. Regulations for the approval of Novel Foods is based on the concept of substantial equivalence. This approach, used by ACNFP, WHO and OECD is based on the demonstration that a novel food produced by or representing GMO is as safe as its conventional counterpart. The levels of variation must be within the natural range of conventional counterparts. This is a rational approach, but needs to be combined with an appropriate labelling strategy to sustain public confidence. For example, a refined oil derived from herbicide-tolerant oilseed rape would be substantially equivalent to the conventional product. However, consumers will demand the right to know that the ingredient is derived from a GMO.

6. The labelling of Novel Foods derived from or containing GMOs must be open and informative. If possible the *type and reason* for the modification should be available to the public to enable them to make informed choices. This could possibly be achieved through a code or symbol system. Labelling should be clear, avoiding statements such as "this product may contain". Consumers will be suspicious if labelling is based on the measurable amounts of product from GMOs, although information on the content should be available for monitoring and enforcement of regulations. Consumers will need to know the provenance of the ingredients in Novel Foods and traceability should apply to GMO derived products, even where substantially equivalent.

7. GM horticultural products will, in many cases, be the GMO itself, e.g., where fresh products are modified to maintain quality on the supermarket or consumers shelf. In some cases, these foods may contain elevated levels of compounds known to have positive health benefits, i.e., functional foods or nutraceuticals. By definition, these products will not pass the test of substantial equivalence, being outside the natural range of variance. Regulation for Novel Foods should anticipate this situation. Full safety evaluation of such products will be required to sustain consumer confidence.

8. Genetic modification offers substantial benefits in terms of environmental enhancement through reduced chemical inputs and health and quality enhancement. For the Horticulture industry to take advantage of the opportunities, the regulatory regime will need to be rigorous, rational and transparent, to reserve public safety and confidence. A regime, which is over-complicated, slow and expensive, or only nationally based, will inhibit the application of this important technology.

4 June 1998

Memorandum by the Embassy of the Republic of Hungary

INTRODUCTION

1. After more than one year of preparation a framework-law had been worked out in 1996–97 in Hungary. The law was passed by the Hungarian Parliament in March 1998. It is going to set in force in January 1999.

2. Although the provisions of the law are originally based on two European Community directives (90/219/EEC Council Directive on the contained use of genetically modified microorganisms and 90/220/EEC Council Directive on the deliberate release of genetically modified organisms into the environment), the subject of the Hungarian regulation is much broader than the EC's one. The scope of the Hungarian regulation covers all kind of genetically modified organisms with the exception of humans. The protected and wild (game) organisms are prohibited to be modified.

3. The act is a framework-law which is going to be backed by several decrees of the competent ministries. The ministerial decrees will adapt in deep details the above mentioned two directives' rules (for example the annexes—forms to fill in by the applicants—of the directives).

APPROXIMATION OF LAWS

4. Following elements of the law can be considered fully or partly harmonised with the provisions of the above mentioned two directives.

(a) *Authorising system*

Permit is obligatory:

- to establish genetchnological laboratory;
- to modify natural living organism;
- to use gmo in contained system;
- to release gmo into the environment;
- to commercialise gmo on the market;
- to export and to import gmo.

(b) *Institutions which are responsible for permitting gmo-activities:*

- independent *committee of genetchnology* (prepares the decisions and gives opinion; consisting of 17 representatives of the competent ministries, of the Hungarian Academy of Sciences, of the National Committee on Technological Development and of the non-governmental organisations).
- *authorities of genetchnology* under the control of the competent ministries (there will be several authorities according to the industries where application of GMO is intended; authorities give the permits, control the application, in certain, defined cases* restrict or ban the gmo-activity, take back the permit, fine).

5. [Authorising responsibility is shared by three ministries—Ministry of Agriculture, Ministry of Welfare, Ministry of Industry, Commerce and Tourism—in accordance with the most common applications of biotechnology. (Biotechnological activities are divided into three categories by the law. These are the following:

- (a) plant-and animal-breeding, food-and feed-production;
- (b) human health-care, medicine-production;
- (c) industrial use not included in the preceding two categories.)

6. The Ministry of Environmental Protection also has an important role as a consultant (veto-authority) in giving an expert opinion on the activities to be permitted.]

1. GMO-activity can be restricted or banned if there is new information relating to the risk of the activity (especially in case of danger to the health or to the environment). If it is banned gmo should be destroyed.
2. GMO-activity-permit can be taken back and the permittee can be fined in case of violation of law or of provisions written in the permit.

7. Deadlines in decision-making on the applications for permit.

In case of activity relating to:

- genetic modification or contained use of gmo: 90 days
- deliberate release of gmo into the environment or commercialisation of gmo on the market: 180 days
- export or import of gmo: 60 days
- establishment of gmo-labs: 45 days

8. Publication of the draft-permit¹ and the permit.²

Deadlines for public comments on the draft-permits (from the date when it was published)

In case of:

- genetic modification or contained use of gmo: 30 days
- deliberate release of gmo into the environment or commercialisation of gmo on the market: 40 days

9. Publication of the finalised version of the permit.

- genetic modification or contained use of gmo;
- deliberate release of gmo into the environment or commercialisation of gmo on the market;

10. Adaptation of the provisions of the Regulation 258/97/EC of the European Parliament and the Council on novel food and novel food ingredients.

11. The law on genetchnological activity amends the Act No. 1995 XC on foodstuffs by adapting the definitions relating to novel food and to labelling of novel food of the above mentioned European regulation.

¹ Draft-permits are published in the official journal of the authority and in two national dailies.

² Permits are published in the official journal of the authority.

OTHER ELEMENTS OF THE LAW

12. A database will be set up for the registration of the relevant information relating to permitted:

- genetic modifications;
- contained use;
- deliberate release into the environment;
- commercialisation;
- establishment of labs.

The data will be provided for by the competent authorities.

13. Products consisting of or containing GMO as well as products derived from GMO will be labelled.

14. In waste-management three categories are differentiated: hazardous waste of biotechnological activity; waste of GMO used in food-production is harmless; waste is to be analysed by the authorities which determine the way of handling and neutralising it.

15. Biosafety officer should be employed by the companies and institutes which deal with biotechnology. Biosafety officer is responsible for fulfilments of the laws and of the provisions written in the permit by the company or institute.

16. Responsibility for the damages caused by GMO-activities is defined in accordance with the Hungarian Civil Code's provisions regarding to liability for hazardous operation (objective responsibility with the exception of vis major).

17. Measures defined in the Criminal Code of the Hungarian Republic are used if the permitted GMO-activity realises a crime.

18. Permits for transporting of GMO will be given in the GMO-activity-permits.

19. In the vicinity of natural protected areas genetic protection zones will be set up where the release of GMO is not allowed.

20. Partial retroactive force: In 60 days after the act on genetchnological activity sets in force, those contained use, deliberate release, commercialisation and import of GMO which were executed before the new regulation would have set in force, should be notified to the competent authorities. The competent authorities will control the notified activities whether these fulfil or not the legal requirements. If the requirements are not met the activity should be banned and restoring of the original environmental situation will be ordered.

21. Ministerial decrees following the act will regulate in details:

- labelling;
- genetic protection zone;
- conditions (technical, technological, environmental, natural protection, health) of GMO-activities;
- procedure and structure of the committee of genetchnology;
- rules of export and import of GMO;
- conditions of employment and education of the biosafety officer;
- provisions for data-registration;
- fees for permits;
- genetchnological fine.

2 June 1998

Memorandum by the Institute of Arable Crop Research

GENETIC MODIFICATION TECHNOLOGY

1. Both wheat and sugar beet were amongst the last crops for which reasonably efficient transformation systems have been developed. There are, therefore, fewer products than might otherwise have been expected. Wheat has been transformed by using a ballistics device (gun). This approach often leads to larger inserts of foreign DNA than the use of *Agrobacterium*-based methods. sugar beet has been transformed in different ways including using *Agrobacterium* vectors. The poor efficiency of almost all techniques has required the use of selectable markers (e.g., herbicide resistance) and has precluded the use of more sophisticated techniques to remove bacterial antibiotic resistance markers. This may change as technologies develop.

CURRENT OR EXPECTED MODIFICATIONS

2. Modification in sugar beet are nearer the market and include herbicide tolerance (to both Roundup from Monsanto and Basta from AgrEvo) and virus resistance. Future targets in sugar beet might include (if suitable genes can be defined):

- Virus resistance; virus yellow is a major economic problem.
- Nematode resistance; these are major economic pests worldwide.
- Aphid resistance; because the aphids carry viruses would have to stop the aphids from damaging the plant sufficient to transmit the virus.
- Production of sugars other than sucrose; this could provide some industrial attraction.
- Stress resistance—particularly drought and frost; drought is the largest single problem for the UK beet crop.
- Control of bolting/flowering; sugar beet is a biennial and is triggered to flower by cold—a barrier to beneficial early planting.

3. Modifications field-tested in wheat include genes for controlling fungal diseases and modified processing properties. Future modifications might include.

- Herbicide tolerance; although neither Monsanto nor AgrEvo have announced such projects in wheat. There are technical opportunities using other herbicides if they are commercially attractive.
- Modified starch and further modifications to seed proteins; already there are commercial plants that separate out the starch and gluten from wheat grain, possibilities exist to enhance the value of both products and to replace imported maize starch.
- Modification of height and straw strength; lodging is still a problem and chemicals to shorten and strengthen the straw are used widely.
- Genes to allow easier production of hybrid seed; novel genetic approaches to make hybrids in oil-seed rape are in commercial trials—these could eventually be adapted to work in wheat, which would greatly enhance the value of the seed market.
- Virus resistance, particularly to soil-borne viruses.
- Nematode resistance.
- Stress resistance.
- Control development; sprouting, malting quality depend on the way seeds develop.

IMPLICATIONS OF THE USE OF GMOs WITH DIFFERENT TRAITS

Herbicide tolerance

4. Because both crops are already tolerant to a wide range of herbicides almost all the acreage of both crops is sprayed with herbicides. GMO herbicide-tolerant crops will increase the range of herbicides available. This change will allow more environmentally friendly herbicides and even less herbicidal ingredients to be used. The result will greatly depend on the circumstances of the crops. Because the GMO crops have a high degree of tolerance they will allow the farmer to wait to see where the weed problems are before spraying rather than, in some cases, having to rely on prophylactic pre-emergence spraying. They also offer interesting biocontrol possibilities for reducing damage from pests without reducing biodiversity and also reducing total pesticide usage.

Fungal disease resistance

5. Cereals are major targets for fungicides in Europe. Really effective disease resistance, which may not be easy to achieve, would lead to a large decrease in the use of fungicides.

Virus resistance

6. Both crops suffer from viruses. The most serious in the long term are those that are present in the soil and transmitted by fungi—e.g., Rhizomania in sugar beet. Because infected soils are almost impossible to disinfect, growing healthy crops on infected soils depends on in-built genetic resistance to either the fungus, or the virus, or both. Some conventional sources of resistance exist within the germplasm but there is considerable potential for a novel GM approach. Some concerns may arise over certain anti-viral approaches, where homologous recombination events occur and give rise to new viruses.

Straw shortening and development in wheat

7. Genetic straw shortening could potentially lead to increased yields and decrease use of synthetic chemicals. Control of sprouting and germination could markedly increase the quality and value of wheat and barley for breadmaking and brewing respectively.

Hybrid production

8. The value of the wheat seed market is much lower than that for hybrid crops, e.g., maize, sugar beet. The low value of the seed will constrain the investment and traits that are devoted to the crop. A hybrid seed market would allow investors to recover the value of their investment. Without hybrid cereals there will be a dependence on the public sector to drive crop improvement by GM technology. This could have adverse effects on the competitiveness of UK agriculture.

GMOs and end products

9. I have not covered very high value chemicals (e.g., pharmaceuticals) which may only be grown on a very small scale. Products, e.g., sugars, which are extracted and purified from GMOs should not contain any trace of the inserted genes in that they contain neither DNA nor protein. In contrast, modifications in seed proteins will be carried through into the final product. There will therefore be different issues to be considered in using and following the products of GMOs in the food chain.

Escape into the wild

10. Wheat is not able to exist in the wild in the UK for more than two or three years at most. It also has no wild relatives in the UK with which it could cross. Cultivated sugar beet rarely survives long in the wild. However, although a biennial crop, a small proportion of the plants in the root crop flower in the first year and, if not eradicated, can give rise to a long-term weed beet problem. Therefore transgenes could become established in weed beet. Wild *Beta maritima* is restricted to coastal margins and there is evidence that cross pollination occurs rarely between these and cultivated beet. These risks of transgene escape are currently being evaluated at IACR.

Memorandum by the Institute of Grassland and Environmental Research**GENETIC MANIPULATION OF FORAGES**

1. There is a need to support the UK livestock production industry via the development of new forage varieties that will maximise the contribution that home-produced plant material will make to the ruminant diet. This will sustain and improve consumer confidence, reduce input costs, and should (in time) improve the quality, traceability and acceptability of the products.

2. At present, the production of new forage varieties occurs mainly via conventional breeding. Increasingly, this is being supported by the application of molecular markers and wide hybridisation techniques to improve access to the existing range of variation within the gene pools of both clover and *Lolium/Fescue* grasses (the major forage species grown in the UK). Currently, genetic manipulation is being used experimentally to delineate specific targets from such programmes but, in IGER at least, under containment conditions.

3. Both grasses and clovers are outbreeders, and have natural populations within the area of cultivation. Specific management systems for seed production have, therefore, been developed to prevent movement of unwanted traits from natural populations into commercial varieties. These techniques would, of course, be equally applicable to controlling any interactions between GM material and natural populations. Work at IGER and elsewhere has been carried out for a number of genes to assess the scale of gene flow across populations. In addition, the targets for all forage improvement in the UK, whether or not GM is involved (persistency, capability with white clover, and quality in terms of animal nutrition) are likely to reduce fitness in the natural environment by, *inter alia*, increasing the requirement for nitrogen to support protein accumulation, reducing competitive ability to generate a better balance with clover, or altering allocation of material away from poorly digestible stem material which, in the wild, would promote reproductive success.

4. Thus, we consider that:

- (a) the development of GM forages is not imminent but will, if permitted, form part of the breeder's armoury into the 21st century;
- (b) the targets for such breeding efforts are unlikely to be directly and positively associated with fitness in natural mixed communities;
- (c) the current regulatory framework is comprehensive enough to address issues regarding out-breeders and the development of adverse traits within natural communities.

July 1998

Letter from the Embassy of Japan

I refer to your letter dated 7 May 1998, addressed to HE the Ambassador.

Thank you very much for giving me the opportunity to contribute to your discussion on GMO regulation in your country.

As the new EC regulation on certain foodstuffs produced from GMO, which does not seem to be clearly detailed, so far, was recently announced, I would like to make a general comment on the issue in relation to the activities of the Japanese industry at this stage.

Several importers of Japanese foods residing in the EU expressed their concern that a bill that "foods should be tested for the presence of DNA or protein resulting from genetic modification and that labelling would be required if the test shows difference from an existing food in composition and nutritional value", which was adopted at a recent EU farm ministers' meeting, might cause adverse effects on import of Japanese foods to the EU. The possible adverse effects include, *inter alia*, delay in delivery and additional expenditure for verification for goods imported from Japan.

Additionally, I enclose the following guidelines (*not printed*) regarding controls on release of GMO or usage of GMO to food, which were prepared by four ministries (or agency), respectively:

(1) The Ministry of Agriculture, Forestry and Fisheries:

[System and Procedures for the Application of Recombinant DNA Crop Plants in Agriculture, Forestry, Fisheries and the Food Industry]

[Guidelines for Application of Recombinant DNA Organism in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries].

(2) The Ministry of Health and Welfare:

[Guidelines for safety assessment of foods and food additives produced by the recombinant DNA techniques]

[List of the products which cleared the safety assessment]

(3) The Ministry of Trade and Industry:

[Guidelines for Industrial Application of Recombinant DNA Technology] * I apologise that there is no English version.

(4) Science and Technology Agency:

[Guidelines for Recombinant DNA Experiments]

Kiyoshi Asahina

Counsellor (Agriculture)

11 June 1998

Letter from the John Innes Centre

1. The appropriateness and efficiency of current regulation at European Union level of:

(a) Research;

— The EU has funded research on GM organisms in agriculture to make safety assessment more scientifically informed (e.g., BAP, BRIDGE programmes). The research has tended to be fragmented across the EU member states, and because of the complex method of choosing and managing research projects within the EU, research programmes have sometimes lacked the optimum level of co-ordination and unity of purpose.

(b) release into the environment;

— The procedures at EU level have been very poor, and have frequently disregarded agreed timetables. There has been considerable political interference in decision making.

(c) novel foods and their labelling;

— At EU level assessments and decisions have been slow and subject to considerable political pressures. This is principally because of the frequent difficulty the regulators have in deciding whether judgments should be based principally on scientific evidence or on public feelings and perceptions.

2. The appropriateness and efficiency of current regulation at the level of the United Kingdom and other/member States.

— Within the UK the regulatory process governing the release and food use of GM organisms has proceeded satisfactorily. ACRE and ACNFP and their Secretariats have generally performed well and efficiently within the constraints of the current EU regulatory procedure. There is some variation in the interpretation of the EU Directives in different EU member states. Some member states place more emphasis on a consideration of potential benefit (in addition to assessing risk) than others.

There are some concerns that the regulation should pay greater attention to impact on agricultural practice and wildlife diversity in the agricultural and wider environment.

3. The most appropriate jurisdictions, for decisions on genetically modified organisms:
 - Within the UK the current system of committees, made up of independent experts advising Government on decisions, works well. Some member states send release proposals to many different organisations for comment. These are then analysed by the appropriate Secretariat (Competent Authority) and they come to a conclusion on the evidence presented. The merit of an advisory committee (as in UK) is that members can debate the issues in detail, and their thought processes can evolve with advances in the science and application.
 - Decision making at the EU level is likely to remain demanding for some time, where there is heterogeneity in the decision making process in each member state (all apply the same EU Directives). It is important that agreed timetables are adhered to within the EU regulatory process, otherwise decisions often take an inordinate length of time.
 - Harmonisation at a scientific risk assessment level is progressing reasonably well. Often delays arise because of the different weighting applied in member states, to matters of public perception and opinion.
4. The effect of regulation on different sectors of the industry and on competition:
 - The indecision at EU regulatory level is having a very considerable inhibitory effect on the development of GM crops for agriculture. The list of GM crops approved in USA is about as long as the list of GM crops submitted for regulatory approval in the EU. The difference is that the decision is pending for most applications on the EU list. Research in the UK is at the cutting edge of scientific development. The sluggishness of application within the EU seriously risks jeopardising the competitiveness of our agriculture in the foreseeable future.

Professor R B Flavell

Director

Dr P Dale

Senior Scientist

19 June 1998

Memorandum by LGC Limited (formerly the Laboratory of the Government Chemist)

SUMMARY

1. DNA methods based on PCR amplification of specific DNA markers of genetic modification have been successfully developed and applied to the identification of a variety of GM foods including processed products derived from GM soya, GM maize, GM tomatoes and GM potatoes.

2. Some, more highly processed, foodstuffs may, however, contain very degraded DNA and/or contain PCR inhibitors, both of which factors may affect the PCR reaction such that there may be substantially decreased assay efficiency, or even no reaction at all. This could result in the reporting of false negative results for GM foodstuffs if appropriate controls and reference standards are not employed. To a certain extent these effects may be overcome by modification of the DNA extraction process and PCR assay design and conditions, at additional analytical time and cost. However, if the GM DNA is removed from the product as with some refined foodstuffs or totally degraded, detection is not possible even if the foodstuff originates entirely from a GM crop.

3. Lower cost "routine" GM food screening options are more reliably applied to raw or moderately processed foodstuffs or ingredients. Typically, batch analysis of these type of foods is offered by analytical laboratories for approximately £100/sample (+VAT). Considerable extra costs are incurred for the analysis of more "complex" samples, generally determined on a food by food basis.

4. Biotechnology developments, including antibiotic resistance gene removal, and the development of alternative GM control elements, coupled with the ongoing drive to market of new GM crops and foods will necessitate further research and development of new GM tests to ensure the continued validity of the PCR testing process.

5. The introduction of a "*de minimis*" threshold for GM material in foodstuffs will necessitate the development of validated quantitative PCR assays; at present these could only be considered semi quantitative. The design of suitable PCR quantitative assays for GM foodstuffs which will have the accuracy and precision to be applied for enforcement of labelling regulations, will pose significant technical challenges, and would require Government funding.

6. In conclusion, the significant challenges to GM food detection by PCR, posed by processed foodstuffs, are such that the food labelling statement “does not contain” in reality should actually state in many cases “cannot be detected and/or quantified using currently available technology”.

INTRODUCTION

What are genetically modified (GM) foods?

7. “GM foods” originate from organisms, generally plants, which have had their DNA altered, or “foreign” DNA introduced by the process of genetic engineering usually for the purpose of:

- Enhanced product quality
- Increased pest resistance
- Introduced agronomic trait

8. The “foreign” DNA introduced during the genetic engineering process (Figure 1) can act as a “tag” or marker for genetically modified (GM) plants. Detection of these “foreign” genetic markers in food can therefore be used as the basis for development of tests for GM foods.

Plant genetic engineering

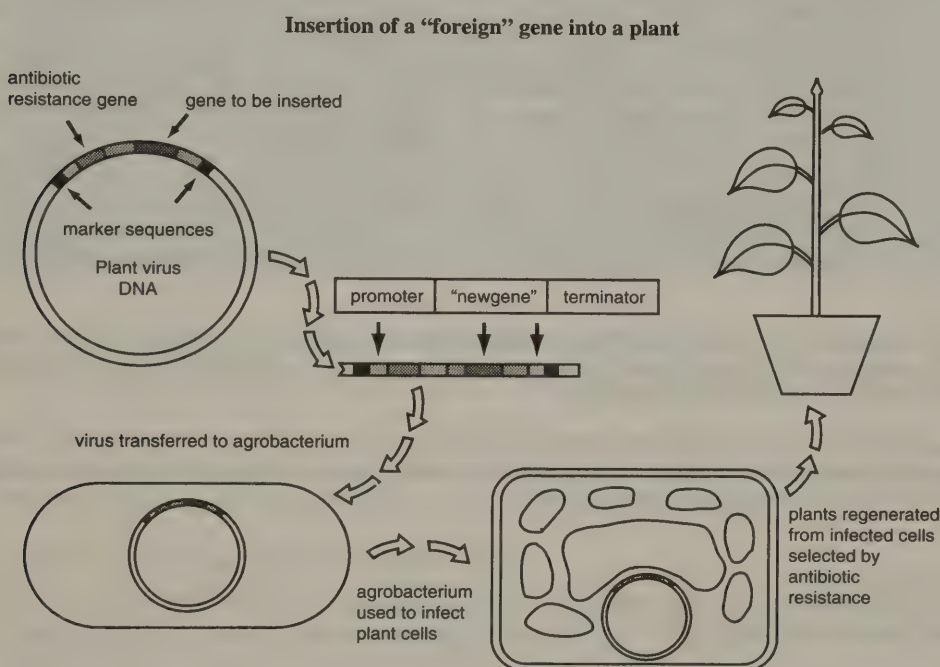


Figure 1. Illustration of a method of production of a genetically modified crop plant by infection with transformed agrobacterium (adapted from Biotechnology for Crop Improvement p7 in Recent Advances in Plant and Microbial Biotechnology, AFRC/NCBE).

9. In a typical genetically modified organism there are usually several DNA markers that may be used for detection:

- the gene(s) introduced into the organism to elicit the required new characteristic; e.g., the gene introduced into Monsanto’s Roundup Ready soya to make the crop resistant to glyphosate herbicide.
- the “start” (promotes) and “stop” (terminator) DNA sequences, which flank the introduced gene and act as “molecular switches” to ensure that the introduced gene functions properly;
- chemical resistance markets, e.g., antibiotic resistance, which are introduced into the plant to aid selection and development of the GM plant.

GM crops approved for field release and food use

10. Table 1 illustrates the great variety of genetically modified plants grown for food production which have received regulatory approval for field release by various competent authorities worldwide (predominantly in the US). Those marked with an asterisk have received EU approval. It is likely that most of these will also be

approved for food use—several already have been, as indicated in the table. GM crops depicted in bold type may be considered as commodity crops which are likely to be mixed with unmodified crops, and/or partially processed in the country of production, as is currently the case the GM soybeans and maize.

TABLE 1
GM crops approved by international regulatory authorities for field release

Crops that have been genetically engineered and approved for field releases worldwide			
Alfalfa*	Cranberry	Peanut	Sugarbeet*
Apple*	Cucumber	Pear	Sugarcane*
Asparagus	Grapevine*	Pepper	Sunflower
Aubergine	Kiwi	Plum tree	Sweet Potato
Barley	Lettuce*	Potato*	Tobacco*
Cabbage	Maize*	Rice	Tomato*
Carrot*	Melon*	Rye	Turnip
Cauliflower*	Onion	Soybean*	Walnut
Chicory*	Oilseed Rape	Sprout	Watermelon
Celery	Papaya	Squash*	Wheat*
Clover	Pea	Strawberry*	
approved for food use		* including EU	

11. These foods can be readily identified as GM in their raw state (see *Detection*), but most of them are likely to be processed to varying degrees and mixed as ingredients in complex foodstuffs which pose more challenging analytical problems (see *Limitation*).

12. As identified in table 1, there are several crops now approved for food use within the EU. GM soybean and maize have resulted in the greatest level of public debate. Issues with respect to detection of these GM commodity crops in foodstuffs are discussed below.

DETECTION OF GM FOODS

Methods for detection of GM foods

13. Various methods have been developed for the detection of genetically modified organisms. Labelling regulations state that GM protein and/or DNA based methods may be used for analysis.

Protein based methods

14. Protein based methods (immunological and enzymic) detect the gene product or metabolites whose production is influenced by the gene product. These methods have two significant limitations so are not routinely employed by most laboratories for GM food detection. Antibodies have to be raised to the specific proteins produced as a result of the genetic modification, and very few relevant antibodies are available. More critically, proteins degrade on processing, so even if antibodies exist, the methods are generally only applicable to fresh, raw foodstuffs.

DNA based methods

15. DNA based methods are the most reliable for the identification of genetic modifications, and have been most widely used. At a practical level, DNA based testing for GM food involves first extracting DNA from the food sample. Some foodstuffs such as tomato puree are more challenging, and it may be necessary to try several extraction and purification procedures in order to extract DNA suitable for analysis. Genetic markers indicative of the genetic modification (as described above) are then detected using a very specific and sensitive DNA

amplification and detection technique called the polymerase chain reaction (PCR) (see appendix 1). DNA sequences called primers can be synthesised in the laboratory that are designed to bind specifically to the genetically modified DNA if extracted from a food sample. The PCR reaction copies, or amplifies, the DNA designated by the primers, which is then typically identified by simple gel analysis and visual detection of specific bands as illustrated in Figure 2.

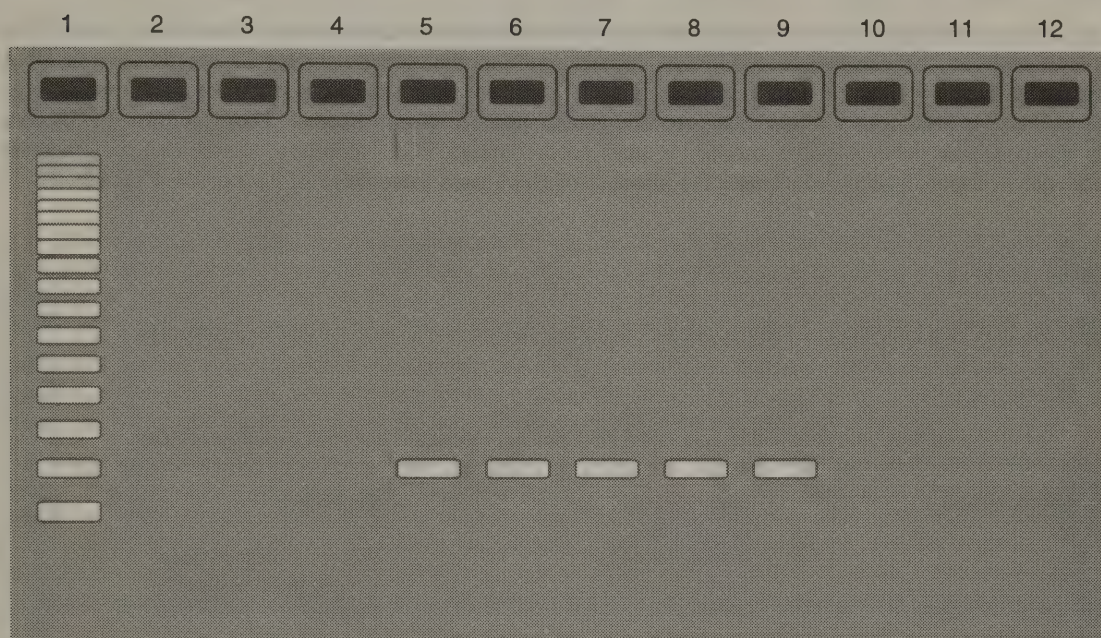


Figure 2 GM soya detection by PCR analysis using primers specific for GM "Roundup Ready" soya. Lanes 2-4 nonGM soya samples, lanes 5-8 GM flour samples, lane 9 GM soyabean, lane 10 oilseed rape seeds

16. DNA is a remarkably stable molecule and often survives food manufacturing processes. Tests can therefore be carried out not only on raw foods but on cooked and processed products.

17. An ideal PCR screening method is designed such that:

- primers selected are specific for genetic elements in a number of GM crops (see Appendix 2 for a table of typical genetic markers used in PCR analysis);
- the genetic element/marker should not occur naturally in the plant or in likely contaminating micro-organism;
- only a small DNA fragment needs to be PCR amplified to allow application to processed samples in which the DNA is likely to be very fragmented.

18. At present, using a limited number of PCR reactions the majority of commercially released GM crops/foodstuffs may be identified (see appendix 3). This generic approach to GM food detection, employing the most commonly used markers for plant genetic modification, has significant advantages in that a specific assay does not have to be individually designed for every single GM crop.

19. However, in order for a GM food testing regime to remain valid, GM targets selected would have to be continually updated to include new/changed "second generation" marker sequences.

20. It is likely that, in future, plant regulatory sequences will be used to control expression of introduced DNA. Similarly pressure on companies to replace/delete genes conferring antibiotic resistance and diversification of transcription terminators will reduce the utility of widely employed markers.

21. Experienced analytical laboratories will be able to continually match the new generation of markers with new PCR tests for GM food identification. However, it is likely that funding will need to be provided by Government for the ongoing R&D necessary to maintain the validity of such PCR based tests in support of GM food labelling regulations. Furthermore, this will increasingly necessitate extended knowledge of the genetic

modification, particularly as more organisms are brought into the food chain, e.g., GM fish, GM micro-organisms. Commercial sensitivities may also limit access to the required information, a potential constraint which may have to be overcome through regulatory action.

Quality control—ensuring valid experimental results

22. When carrying out tests on genetically modified organisms it is important to minimise the potential for incorrect analysis. This can be achieved by carrying out appropriate imitation control PCR reactions, using DNA primers designed to recognise whether any plant DNA is present and/or the DNA from the specific crop, e.g., soya or maize is present in addition to the specific genetic modification of interest. These additional PCR tests help guard against false negative results (as may occur through PCR inhibition, see below) and increase confidence in the analysis by confirming the presence of DNA from these crops in the extracted sample.

PCR application to a variety of foodstuffs

23. At LGC we have successfully applied PCR to the analysis of a wide variety of foodstuffs:

TABLE 2

Examples of processed foods from which DNA has been extracted and PCR amplified at LGC

Soya protein isolates	Tomato soup	Tinned fish ¹
Soya grits	Tomato puree ¹	Pate
Lecithin	Tomato ketchup	Processed meat products
Beanfeast	Sundried tomato	Canned meat products ¹
Maize starch ¹	Chips	Petfood
Maize gluten	Potato salad	Animal feeds
Rice	Crisps	Honey ¹
Pasta and noodles	Smash	Biscuits ¹
Flour samples (maize and soya)	Oxo cubes	Confectionary bars ¹
	Powdered soups	

¹ Indicates sample types where DNA extraction and PCR are highly variable, and success cannot be guaranteed.

24. As indicated with ¹ in the above table many processed foodstuffs give highly variable results with PCR. The potential reasons for this are discussed below.

25. DNA detection methods are not applicable if, in the course of the food production and/or processing, plant DNA is *completely* separated or destroyed e.g., refined sugars or oils. However, again for these types of food product, the extent of processing may give rise to variability in GM detection. For example, DNA may be able to be extracted from raw pressed oils but not the heavily refined oils, and LGC's practical experience with maize starch has indicated that GM maize could be identified in samples from some sources but not others, presumably due to differences in processing.

LIMITATIONS OF PCR DETECTION FOR GM FOODS

26. Although PCR is a potentially powerful detection assay for the rapid, sensitive and specific identification of GM foods, food processing can significantly influence the validity of the PCR assay.

DNA degradation

27. Various factors contribute to the degradation of DNA in processed foodstuffs: chemical, physical and enzymatic e.g.

- prolonged heat treatment such as autoclaving used in the canning process, may result in DNA hydrolysis which fragments the DNA, or modifies the chemistry of the DNA in such a way that the PCR process may not work. For this reason canned products can give inconsistent results.
- increased chemical modification and hydrolysis of DNA at low pH (e.g., vinegar). For example, these factors make tomato puree (and related tomato products such as ketchup) extremely difficult

to work with; results are inconsistent and we, in common with many other workers, often fail to achieve successful amplification even with primers designed to detect *any* plant DNA.

- enzymatic degradation of DNA by nucleases may also occur on prolonged storage of fresh foodstuffs.

PCR inhibition

28. A recognised problem in using PCR methods with foods is the presence of PCR inhibitors that reduce the efficiency of the genetic amplification process. These include many common food components:

- cations e.g., Ca^{2+} , Fe^{3+} ;
- trace heavy metals;
- carbohydrates;
- tannins, phenolics;
- salts e.g., NaCl, nitrites.

29. Work at LGC, in addition to studies reported in the literature, indicates that the degree of PCR inhibition is to a great extent dependent on the food type, e.g., boiled ham shows little or no inhibition, whereas various kinds of soft cheese completely inhibit the reaction. This could lead to potential analytical problems if for example three pies with fillings of ham, soft cheese, soft cheese and ham were analysed for GM soya content.

30. Without the proper reference standards and PCR controls, as outlined above in section 2.2, PCR inhibition may easily lead to false negative results, particularly if the GM food analysis is being undertaken by laboratories with insufficient experience with food analysis by PCR to recognise the problem.

31. It is sometimes possible to overcome these inhibitory effects by extensive dilution of the DNA extract, however, this may not be an option when the amount of DNA in the sample is limiting. In these cases, further purification of the DNA, or the addition to the reaction of PCR enhancers may reduce the level of inhibition. Knowledge of likely inhibitory components in foodstuffs can inform the type of analysis undertaken and modifications to the routine extraction and PCR procedure. Such special analytical modifications may prevent false negatives and allow a higher level of confidence in the result obtained, but add time and cost to the analysis.

32. It should be noted that if a foodstuff labelled “does not contain [GM material]” becomes subject to forensic analysis as a result of trading standards enforcement of labelling regulations, it is likely to be subjected to more exhaustive tests than afforded by routine screening methods.

Implications for validity of GM food analysis by PCR

33. Many foodstuffs which may need to be labelled will be subject to varying degrees of processing, frequently with the addition of ingredients which result in a complex food matrix. Detection of DNA by PCR will therefore probably be influenced by the relative extent of PCR inhibition and DNA degradation on a food by food basis.

34. There are very significant challenges in the detection and quantification of processed foods and food components even with complete knowledge of the processing history of the sample, its origins and purity. The possibility of identification of processed food as containing GM source ingredients should ideally be elucidated on a case by case basis. Given the variety and complexity of foodstuffs available in today's markets this would pose a considerable expense for the industry.

35. If absolute traceability of ingredients can be ensured during food preparation, then testing for genetic modification in less processed or raw ingredients which are being added into the food product would be a more reliable option for determining whether the final food product contains GM material. This can be achieved from the ingredients if traceability exists and, in fact, a wide range of related products could all be assessed from the smaller range of initial ingredients, saving time and money.

QUANTIFICATION ISSUES

36. In common with other food labelling regulations a *de minimis* threshold has been proposed for the labelling of GM foodstuffs, to potentially allow for the adventitious “contamination” of a foodstuff or ingredient through the food supply chain. Such a threshold, which has been considered at 1–3 per cent, in line with other food legislation, would necessitate quantitative analysis of [GM] foodstuffs.

37. In consideration of a *de minimis* threshold for the presence of DNA [or protein] resulting from genetic modification the following issues should be carefully considered:

PCR detection limits

38. Detection limits were determined for GM soya using serial dilutions of purified GM soya DNA with non GM soya DNA to stimulate different mixtures of GM and non GM soybeans. Detection limits were determined to increase from 1 per cent to 0.01 per cent as the extent of PCR amplification was increased above standard

practise (Wurz and Willmund, 1997). At LGC we have also conducted experiments to determine the limit of detection for GM soya flour in admixture with non-GM flour. Using standard PCR methodology a 0.1 per cent level of GM soya flour DNA was detected.

39. Food matrix effects on the relative limits of detection possible with PCR were demonstrated in experiments carried out by Greiner and Konietzny (1997). These researchers reported experiments in which they introduced "foreign" (*E. coli*) DNA into a baking process. DNA was extracted at different stages of processing, and PCR employed to detect the introduced *E. coli* DNA.

TABLE 3
*Experimental results demonstrating that the limit of detection by PCR
of "foreign DNA" is significantly increased by food processing*

Processing stage	Limit of detection by PCR (gene "copies")
Pure DNA	1
DNA added to rye flour	100–150
Baked	not detected

40. These results clearly demonstrate that at each successive stage of the baking process it becomes more difficult to detect the inserted "foreign DNA", even though the same percentage of DNA is present as an ingredient at the end of the process as at the start. It is expected that the same situation would apply in the case of detection of "foreign" GM soya flour in bakery products.

41. Therefore, the evidence suggests that the ability to detect GM residues in food significantly decreases as the level of food processing increases. If the requirement in the proposed labelling regulations would be for a 1 per cent cut off for the particular food product, then in more highly processed foods which may actually contain a high percentage of for example GM soya, the level of detection may be below this threshold value, and the product could potentially be labelled "does not contain GM soya".

42. There is therefore a requirement to establish the relative limits of detection (under standardised PCR conditions) for different types of foods, to inform the proposed legislation.

Quantification of amount of GM material by PCR

43. Future EU legislation is likely to set limits for the percentage of GM material below which food can be labelled as not containing GM Derived material. Enforcement of such legislation will require development of testing procedures which can accurately measure the amount of GM material in food samples.

44. Precise and accurate quantification of the amount of GM material in any given sample is analytically very demanding. However, this would be required for enforcement of labelling regulations, which would necessitate, the confident determination of the level of GM material in a food for instance, 0.5 per cent may be below the threshold value for labelling whereas 1.5 per cent may be above. Exact PCR quantitation is essentially still at the developmental stage for food analysis, and is not yet routinely possible.

45. Current quantitative PCR methods are of two major types:

- (1) Threshold detection analysis is really an extension of limits of detection analysis and involves PCR application of standards containing known amounts of GM material alongside unknown samples. Instead of looking for presence or absence of bands against known standards, the relative yields of amplified product from the standards and unknown samples are compared to enable quantitation.
- (2) Quantitative competitive PCR (QCPCR) relies on the co-amplification of known amounts of a second DNA target or mimic. In this competitive amplification, both targets have the same PCR priming sites and compete for the available reagents in the PCR reaction. The result of the competitive nature of the reaction is that the relative yield of target and mimic can be related to the starting ratios of the two. By competing an unknown amount of one target with a known dilution series of a suitable mimic, the amount of target GM DNA can be calculated.

46. An advantage of QCPCR is that amplification of mimic and target are carried out in the same tube providing an internal PCR control. The disadvantage of QCPCR is that development of PCR mimics can be technically challenging and new mimics will have to be generated for each new target. In contrast, quantitation using threshold detection analysis only requires access to the PCR primers used for standard detection and standard DNA samples of known composition.

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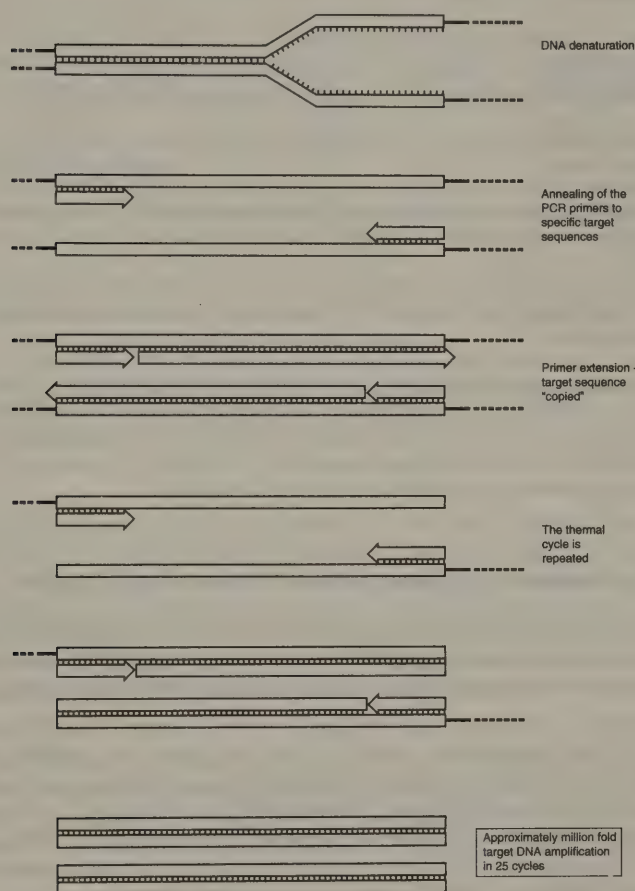
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APPENDIX 1

The Polymerase Chain Reaction (PCR)



APPENDIX 2

Typical genetic markers for PCR detection of GM foods

Marker	Gene target	GM Crops/food
Antibiotic resistance	Kanamycin® (nptII) Ampicillin®	Several, inc. Tomato, oil seed rape, potato maize
Herbicide tolerance	Bar gene (BASTA tolerance)	Oilseed rape
Genetic elements	CaM35S-promoter (P-35S) NOS 3'terminator	Many, e.g., tomato, maize, soya Many, e.g., tomato, maize, soya
Specific genetic modification	Anti-sense polygalacturonase CaMV 35S promoter and CP4 EFSPS gene Synthetic Bt cryIA gene	Tomato (Zeneca) GM "Roundup Ready" Soya GM Bt Maize
Plant	Universal 18S rRNA (PUV) chloroplast rubisco (MAG) Seed storage gene (MDB) maize high mobility protein Lectin	All plants All plants Brassica specific Maize specific (?) Soya specific

APPENDIX 3

Generic PCR test for GM food products

Genetic elements	Number of individual PCR tests	Identifiable products (total 28)
P-35S	1	22
nos 3'	1	16
P-35S, nos 3'	2	26
P-35S, nos 3', E9 3', als	4	28
<i>npt</i> II	1	17
P-35S, <i>npt</i> II	2	25
P-35S, <i>npt</i> II, nos 3'	3	26
P-nos	1	7
P-35S, P-nos	2	25

The table demonstrates that by using a limited number of PCR reactions the majority of commercially available genetically modified crops can be detected.

For example, by using a combination of a P-35S primer set and a nos 3' terminator primer set, 26 out of 28 commercially available products can be identified.

P-35S = promoter from cauliflower mosaic virus (CaMV 35S);nos 3' = terminator of nopaline synthase gene (from *Agrobacterium tumefaciens*);E9 3' = 3' sequence of small subunit of rbcS (ribulose-1,5-bisphosphate carboxylate);als = acetolactate synthase (sulfonylurea tolerance);*npt*II = neomycin-3'-phosphotransferase gene from Tn-5;P-nos = promoter of nopaline synthase gene (from *Agrobacterium tumefaciens*).

Letter from the National Office of Animal Health Limited

1. NOAH represents the Companies of the UK which Research, Licence, Manufacture and distribute animal medicines in the UK. Our member companies supply 96 per cent of all the animal medicines licensed for sale in the UK. Included among our members are all the major research based international animal medicine companies.

2. Following our telephone conversation on 18 May, I write to record NOAH's potential interest in the above inquiry. Although NOAH does not have within its remit the genetically modified crops or animals which will form the major focus of this inquiry, aspects of Biotechnology can occur in the production of Animal medicines which are used for the prevention and treatment of farm animals. Such uses are already highly regulated by EU law, notably Directive 81/851 as amended, and are generally regarded as uncontroversial and beneficial. *NOAH and its members wish that their interest should be noted, and requests that we are advised and invited to give evidence should the inquiry be extended into these areas.*

3. The principal ways in which Biotechnology can be applied to the development and production of animal medicines are:

Vaccines

4. With minimal fuss a number of "Biotech" vaccines have already been introduced to the market, most notably the first successful vaccine against Aujeszky's disease in pigs. The opportunities for gene technology in this area are very great—both to provide vaccines for diseases resistant to conventional vaccine technology, and longer-term, to provide replacements for existing chemical therapies. It is already forecast, for example, that Biotechnology could enable the development of vaccines to replace chemical wormers and even to protect sheep from scab. The potential benefits in terms of convenience, operator and environmental safety are enormous.

More efficient production of medicines

5. It is already the case that many traditional antibiotics are produced using cultures where the parent organisms have been genetically enhanced to provide higher production levels and less waste. The resulting antibiotic is no different but the costs are contained.

BST provides another example—whatever one's views on the product, the fact is that biotechnology provided the ability to manufacture a chemical compound which could not be manufactured by conventional chemistry. Human insulin is perhaps a less controversial example enabling necessary medicine to be produced cheaply in large quantities, without the risks inherent in extracting the product from animal (or human) cadavers.

Biotechnology can also be employed to improve production of medicine ingredients, such as glucose which is produced using enzymes developed by Biotechnology.

New Medicines

6. With the concerns over potential resistance to existing antibiotics, genome technology is already providing the prospect of a new generation of antibiotics specifically targeted to by-pass the resistance mechanisms of pathogens. While the initial benefits will be for human medicine, longer term the techniques will also be applied to animal diseases. In the meantime success in counter developing such products to resistance in human disease will undoubtedly reduce the pressure on necessary antibiotic use in agriculture.

Diagnostics

7. Although such products are not strictly regarded as “medicines”, better, more precise and hence more effective treatment of disease depends on correct diagnosis. Furthermore control of residues in food, cheaply and easily, can be assisted at farm and manufacturing level by the availability of simple and accurate testing systems.

Biotechnology is already being used to develop testing “kits” which will enable the more discerning use of medicines and the checking of produce.

Mr Roger R Cook

Director

19 May 1998

Memorandum by Nestlé UK Ltd

1. INTRODUCTION

Nestlé UK is the British operating business of Nestlé SA, the world's largest food company. In the UK, we manufacture and distribute, via retail and catering outlets, import and export products in virtually every sector of the food and drink industry. Our brands include such household names as Nescafé, Rowntree, Crosse & Blackwell, Buitoni, Findus, Lyons Maid, SunPat, Gales, Perrier and many others; we also supply a range of major retailer private label products. In the UK, we employ some 15,000 people, in over 20 factory and head office establishments, with an annual turnover of £1.7 billion. World wide, Nestlé employs approximately 220,000 people, operates some 500 factories and has an annual turnover of approximately 70 billion Swiss Francs.

Our own internal structure and the increasingly global nature of world food trade dictate that we source our raw materials and finished products on a truly international basis. Our European factories operate, similarly, on an international basis and our production within the UK may equally be destined for European consumption as for the domestic market. Likewise, products sold in the UK may well have been produced elsewhere within Europe.

Increasingly, therefore, we perceive Europe as a single trading entity and, in the area of regulation in particular, the need for a single framework of equitable, enforceable rules is paramount.

We therefore welcome the opportunity to contribute our comments to this inquiry.

2. SUMMARY

2.1 Nestlé is committed to the *responsible* use of foods and food ingredients derived from genetic modification. It is also fully committed to openness and transparency in this use and in dialogue with other parties.

2.2 Current regulations impose significant restrictions on research, particularly when viewed on a global basis.

2.3 The UK model (ACRE/ACNFP) for controlling release into the environment has worked well and should be used as the basis for international harmonisation in order to remove current confusion and facilitate global trade.

2.4 The current EU framework for labelling GMOs and their derivatives—despite recent developments—remains ambiguous and incapable of uniform, meaningful application. Further consolidation of existing requirements is now urgently required, whereby *principles* applicable to current and future approval will be established.

2.5 Codex Alimentarius should be the focus for internationally agreed safety and labelling procedures/mechanisms and requirements.

3. DETAILED COMMENT

3.1 *Nestlé Position on Genetic Modification*

New and creative solutions will be required to feed an ever-growing world population with affordable and wholesome foods in an environmentally sustainable way. As one of the world's major users of agricultural produce, Nestlé has been a pioneer in encouraging more efficient and sustainable farming methods, especially in the developing world, where we operate more than 100 factories.

We fully recognise that biotechnology, including genetic modification will be one of the principal tools available to meet these challenges. Traditional biotechnology such as plant and animal breeding has a long history and the use of fermentation to produce preserved products such as cheese, pickles, bread, beer, salami, etc., is well established. Genetic modification has evolved from these traditional processes and allows improvements to be made rapidly, precisely and safely.

Although Nestlé does not directly produce its own raw materials, we are firmly convinced that the responsible control and use of this technology guarantees safe products which will bring substantial benefits to farmers, industry and consumers alike. Nestlé has therefore decided that it will use genetically modified crops and their derivatives, taking fully into consideration local legislation, consumer demand and concerns and the global supply situation.

As a responsible and responsive company, Nestlé encourages transparency and welcomes open dialogue with consumers. We are actively co-operating with suppliers, other food manufacturers, retailers, authorities and consumers in activities aimed at informing the public about developments arising from genetic modification.

Futhermore, although we see no safety or scientific justification for specific labelling we have recognised the legitimate consumer interest for this information and have commenced a programme (in addition to any legal requirements) to indicate the use of ingredients produced with the aid of genetic modification on the label wherever practicable.

Our business is based on offering products tailored to meet the diverse needs and preferences of consumers in all parts of the world. Whatever the technology or raw material, Nestlé only uses ingredients which meet the highest international standards and which comply with all legal requirements. It is therefore essential that these standards and legal requirements are maintained by the authorities and perceived by consumers to be adequate, increasingly on a global rather than a national basis.

3.2 *The Appropriateness and Efficacy of Current Regulation*

(a) *Research*

Nestlé UK is not directly involved in research on genetic modification. However, Nestlé operates a number of research establishments around the world and, in particular, has an establishment dedicated to plant breeding in France. Gene technology is one of the tools available to this team.

We believe that the application of Directive 90/219 on the contained use of genetically modified organisms has imposed undue restrictions on plant breeding at the research level. We would therefore welcome a review of this legislation, recognising at the present time that such a review could well introduce political, in addition to scientific, considerations.

As major users of agricultural raw materials, we are adamant that any agricultural research base within Europe must be at the forefront of science and technology, whilst retaining the principles of safety and good environmental practice as fundamental criteria.

(b) *Release into the Environment*

Nestlé UK follows closely the work and reports of the UK Advisory Committee on Releases into the Environment (ACRE); we are impressed by the professionalism of the committee and the presentation and information contained in its reports.

The previous voluntary scheme within the UK has formed the basis of a European system for approval of release of GMOs. However there have recently developed obvious and confusing overlaps between Directive 90/220, the Novel Foods Regulation 258/97 and more recently Regulation 1813/97. The very recently agreed regulation referring specifically to Monsanto Soya and Novartis Maize, whilst clarifying to a certain extent provisions relating only to these two products does not apply to further products approved in the interim period.

There is a very clear need for the requirements of the various regulations to be consolidated and harmonised. Furthermore, there is a clear and urgent need for European mechanisms to be speeded up in order that the present confusion in trade arising from varying numbers of products approved for use within the USA, Europe and other parts of the world be reduced to a minimum.

This issue is severely compounded in the case of commodity crops such as maize, soya and rapeseed where there are already varieties approved in the United States and Canada, which are not fully approved within the European Union. As users of derivatives of these crops, the legal status of these derivatives remains unclear—certainly the labelling provisions (see later paragraph) are confused.

(c) *Novel Foods and their labelling*

We do not believe that genetic modification in itself presents any new food safety risk or that foods and food ingredients produced with the aid of genetically modified organisms represent a special class of new foods. They should be subject to the same type of risk assessment as any other new food product and its intended use, whatever the method of production which has been used.

We therefore believe that the scope of the Novel Food Regulation 258/97 is appropriate as a means of achieving a harmonised approach to the approval of all Novel Foods and as a basis for ensuring both consumer confidence and fair trade.

However, the labelling requirements defined under Article 8 of this regulation were defined in extremely subjective terms and left open to potentially very wide interpretation. This interpretation is further confused by the reference in Article 5 to “substantially equivalent”, whereas Article 8 refers to “no longer equivalent”; there is a difference of meaning between these phrases but the extent and significance of this difference is totally unclear.

In order to clarify the status and labelling requirements of Monsanto Round Up Ready Soya and Novartis Bt-maize a further regulation has recently (26 May) been agreed.

In our opinion, this latest regulation should now be consolidated with the requirements under Directive 90/220, Regulation 258/97, Regulation 1813/97 and the *underlying principles* converted into a single global regulation which can be, and will be, applicable to all future approvals of genetically modified crops and their derivatives. Several crops previously approved in the United States have recently been notified to the EU authorities and fall within a legal lacuna.

We believe the aspect of “equivalence” to be fundamental to the whole question of labelling of Novel Foods. It is of some concern, therefore, that the EU Regulators appear to have applied a far stricter interpretation to this term than is generally recognised internationally.

Notwithstanding the current regulatory requirements for labelling of Novel Foods and derivatives we remain concerned as to how these regulations will be enforced in practice.

We have frequently stated that a general principle of labelling is that it must be accurate, truthful and meaningful; the legislation must be capable of uniform interpretation and it must be uniformly enforced. We do not believe that the current regulation will meet these criteria until further detailed requirements have been elucidated.

In particular, as indicated in the Council Minutes, the question of thresholds and agreed methodology will be paramount.

We would be pleased to have the opportunity to comment further to your committee on this, should the committee so wish.

3.3 *Appropriateness and Efficacy of Current Regulation at the level of the UK and other Member States*

We have indicated previously our belief that genetic modification will, in the longer term, offer potentially enormous benefits at all stages throughout the food chain from primary agriculture through food processing to final product improvements, whether nutritional or quality related.

However it is equally clear that in these early days of the technology, there are widely differing views as to the need for regulation and/or information about the products.

It is inevitable that the early introduction of genetically modified crops will carry improved agronomic traits. The benefits to the consumer will not, therefore, be immediately apparent. Equally, the interpretation of “equivalence” differs widely between interested parties. This has led to the wide divergence of approach between the EU and the USA/Canada, with the consequential difficulties relating to the supply of commodity crops such as soya and maize.

The EU cannot isolate itself from world commodity trade and the more the EU legislation diverges from that of the USA, Canada and the rest of the world, the greater will become the difficulties in sourcing commodity on a global basis.

This will place additional financial burdens on our industry, and consequently consumers, without generating any tangible benefits.

The initial clamouring for segregation of crops by some parties in Europe has not been modified (at least in words) to the “holy grail” of traceability. This is equally an overly bureaucratic requirement which, at the end of the day, does not meet consumer requirements but adds unnecessary costs to the food chain.

In the longer term it will be essential for authorities, industry and all interested parties to re-establish credibility in approval mechanisms, the safety of the products and the integrity of the food chain. In this way specific labelling requirements may be progressively relaxed and greater emphasis and reliance placed upon alternative means of supplying relevant information to specific interested consumers via modern technology such as carelines, bar-codes, etc.

3.4 *Appropriate Jurisdictions for Decisions on GMOs*

Many of the plants (and no doubt in the future animals) which have been or will be modified by gene technology form the basis of international trade, whether as commodities themselves or as components of final foodstuffs. It is therefore imperative that the regulation of these products, particularly from a safety viewpoint, should be controlled at as high an international level as possible. This might best be done via the FAO/WHO Codex Alimentarius mechanisms. If global agreement to the principles can be achieved, these should then form the basis of local regulation and thus equivalent treatment of genetically modified organisms around the world.

We are confident that appropriate and adequate mechanisms for safety evaluation exist in the Western world but are not aware of similarly thorough controls existing in China and the Far East where considerable developments in this area are being made. We believe it would be an essential step towards ensuring consumer confidence in the technology, and hence its global acceptability, if the Oriental developments fell to be treated in an equivalent manner.

3.5 *The Effect of Regulation on Competition*

Any legislative controls/regulations must be capable of uniform interpretation and be equitably enforced across their range of application. Providing this is done, there should be no undue imbalance of impact on any sector of the industry.

Problems will arise at an international level when local legislation (albeit European based) is out of line with other geographic areas. This increasingly appears to be the case with regard to genetic modification.

With increased internationalisation/globalisation of food manufacture and trading, it will be inevitable that business will move from one location to another if undue cost pressures are imposed upon it. This will apply both to research and development and food manufacture itself.

Future regulation in this area must remain based on scientific considerations, albeit tempered by a political recognition of the sensitivity of this technology, and must be applicable to all relevant stages of the food chain, regardless of the size of the enterprise. Derogations from the legislation should be minimal if any and, if granted, must in no way prejudice the consumer confidence in the totality of the regulatory control over genetic modification.

4 June 1998

Memorandum by Novartis UK Ltd

THE APPROPRIATENESS AND EFFICACY OF CURRENT LEGISLATION ON RESEARCH

1. Working practices and environmental safety of work with GMOs in research is governed by three basic EU directives 89/769, 90/219 and 90/220 and many derivatives of these.

89/769 deals with workers safety;

90/219 deals with the environmental safety of work done with GMOs in contained environments: the laboratory, the glasshouse, animal houses, factories, hospitals, etc;

90/220 deals with environmental and human health safety aspects of work done on GMOs outside the commercialisation of GMOs. This is not correct. Most of the regulatory work generated by 90/220 covers *research* done with GMOs in the field.

2. FIELDS OF RESEARCH COVERED BY THESE DIRECTIVES

- Medical research involving genetically modified organisms. A key case is the use of genetically modified mice as disease models for human diseases.

- Medical research on xenotransplantation.
- Pharmaceutical research on human, animal and plant pathogens.
- The basic study of human, plant and animal pathogens.
- Research on plants, animals and micro-organisms involved in agriculture and food production. The most visible targets of such research are agricultural crops, but micro-organisms such as yeast, bacteria and fungi are as important targets.

3. All the above are fields of applied research. Most of the use of genetically modified organisms in a research setting happens in basic research projects, the only aim of which is to obtain insight into the development, behaviour, ecology of living organisms.

4. A special case is the use of genetically modified organisms in education. When 90/219 was developed (1988–90) it was almost inconceivable that experiments with GMOs would soon become part of the basic curriculum in higher education in life sciences. Undergraduate training in biology *without* experiments using GMOs is almost unthinkable today. All training experiments of course are done with micro-organisms at the lowest risk category. But because European regulation is based on the premise that the process of rDNA techniques might induce unique risk factors not encountered with any other form of biological experimentation (against the scientific consensus) there is no *risk-free* category for GMOs. This meant that in practice work with micro-organisms that had been the standard work horses for biology training suddenly was declared potentially dangerous, against all evidence to the contrary, and governed by new rules.

5. In most EU member states, awareness of this situation was so low that it took years for government and academic authorities to realise that much of their science training had suddenly become technically illegal. They had not foreseen budgetary measures to implement the safety standards set up by the new regulation. Most EU member states have not foreseen any training of their new students in life sciences on the regulatory framework under which they will work during their professional careers.

6. Many of the safety measures prescribed in 90/219 and its successors have had relatively little impact on the work done in contained environment in a company setting. The containment measures and working procedures prescribed in this directive have to a large degree followed those already known to scientists such as the GLP (good laboratory practices) and GMP (good manufacturing practices) regulations in force in the pharmaceutical industry. For work with potential dangerous organisms such as lethal pathogens, the isolation requirements closely follow those already used successfully in earlier legislation. It has been asked why there had to be an additional layer of regulation for these activities, since they basically lay down an additional layer of paperwork covering the same measures.

7. It is different for the application of 90/219 in academic research. The bulk of this research has traditionally been done with organisms that are generally considered safe to work with, such as laboratory strains of the bacteria *Escherichia coli* and the bakers yeast *Saccharomyces cerevisiae*. Suddenly much of this research became technically dangerous, not because there had been an incident or any other indication of possible risk, but because there had been a new regulation, which is based exclusively on a hypothetical risk evaluation not supported by any experimental evidence and an extreme interpretation of the precautionary principle.

EXPERIMENTAL RELEASE IN THE ENVIRONMENT

8. Most experimental releases in the field in an industrial setting involve the development of genetically modified crops, with the ultimate goal of developing new commercial varieties. Traditionally, new genotypes are tested extensively against relatives of proven performance. The introduction of directive 90/220 introduced new rules on isolation of the material, on its disposal and on post experiment monitoring. This has made experimental evaluation of genetically modified crops much more expensive. It also required that agronomic research stations that accepted GMOs in their work had to develop new safety infrastructure.

9. The problem is compounded by the fact that much of the field research on the agronomic behaviour of crops is not done by the companies themselves, but has traditionally been subcontracted to private or public experimental stations that were not technically ready to work under the new regulations.

10. Field research with GMOs in public research institutions has been severely affected by the directive 90/220. When this directive was negotiated little attention was given to the fact that much of the early research in the field was done in public research institutions. Legislators worked from a silent assumption, never publicly challenged, that almost all this work would in the future be done by companies that are used to work under the severe constraints imposed by a restrictive regulatory framework. These companies often have specialists in place to handle the administrative load of compliance with regulations, including the monitoring of compliance with requirements.

11. It was not much noticed that there was great excitement among public scientists about the opportunities offered by the use of genetically modified plants and microorganisms for basic field studies in ecology, physiology and population genetics, among others. Academic research is ill equipped to work under heavy regulatory constraints. Its decentralised nature makes it difficult to develop the expertise in handling the regulatory requirements, and the constant funding problems force hard choices between investing in research or

in regulatory compliance. The result has been that fieldwork with GMOs in academic institutions still represents only a tiny fraction of total research done on them. What is done is mostly concentrated in a few research institutions that have invested in setting up a regulatory compliance infrastructure.

12. This has direct consequences on our knowledge of potential risks associated with GMOs. The bulk of this research is done in contained environment, or in the form of computer models. Very little research is actually done in the field, at least in part because of the restrictions imposed by the regulations. This leads to the situation where the regulations make it very difficult to test their own validity in real life situations.

COMMERCIAL SCALE RELEASE IN THE ENVIRONMENT

13. This is governed by 90/220, part C. No GMO can be released on a commercial scale without a comprehensive risk assessment. This automatically includes series of field trials done under the requirements of 90/220 part B. Over the years several new directives have refined the procedures associated with 90/220. It sets up an administrative process to assess risk, based on the scientific method.

14. However, it has procedural flaws that have become clear over the past three years, as the first generation of genetically modified crops have moved through the process. After the end of the risk assessment process, there is no provision for evaluation of its conclusion in the broader context of a cost benefit analysis or of a comparative risk analysis.

- 90/220 is a risk assessment, not an environmental impact analysis. The technical analysis of an application for field release does not take into account the potential environmental benefits of a new GMO.
- It is scientifically impossible to prove the absence of risk (although several environmentalist groups are asking just that). Any application for introducing to the market will therefore come through the scientific risk evaluation process with a report stating that the risk is small, even negligible, but never zero.
- In the European system, any file that has not received unanimous approval in the administrative process (and the positions of Austria and Luxembourg make unanimity impossible for most files) moves on to the political level for decision making. Nowhere in this transfer is there a place where the risk assessment can be set in the context of the total impact of the new crops. There is in other words no provision for companies to present their products in such a way, as the only dossiers they can introduce in the system officially are the risk assessment files linked to directive 90/220 and the novel food regulation 97/258 (see below).
- As political decision-makers never get to see an environmental cost-benefit analysis as a basis for their deliberations, the only basis they have for decisions is the concept of *acceptable risk*. There is also no provision for a comparative risk assessment of the hypothetical risks of the new product against the risks associated with existing products and techniques.

15. This leads to counter productive decision-making. For example, the present controversy over insect resistant crops totally disregards the fact that these crops were developed to widen the options for insect pest control, and that this in most cases results in reductions of pesticide use. There is no place in the European decision making process to evaluate these different options. In fact, GMOs are treated from the premise that they have no potential for environmental benefits at all, which is absurd. The large-scale introduction of insect resistant cotton in the USA has reduced the use of chemical pesticides on this crop by one-half to two-thirds, depending on the region. Nowhere in the European evaluation process is there room to find out if some of the GMO crops could do similar things to European agriculture.

16. Another major flaw of directive 90/220 is that it does not formally lay down rules for monitoring after commercialisation of a genetically modified crop. There is a broad consensus in the field that good monitoring makes good business sense as well as being environmentally sound. Companies have invested heavily in these products, and want them to be effective for a very long time.

17. Post marketing product stewardship is not new to the seed sector. Much of the so called traditional breeding over the past half century focused on developing varieties with new resistances against pests and diseases. It is well known among plant breeders that sooner or later a disease will overcome the resistance of the crop. This is a logical consequence of the theory of evolution by natural selection. Therefore, breeders and seed certification bodies have for a long time had networks for gathering information on the behaviour of varieties, to provide them with early warning if a resistance shows signs of weakening. This often gives them time to introduce new resistance genes in new varieties before the problem starts having an economic impact. There is every indication that the same system can be used with success for genes that were introduced through modern gene technology.

18. The absence of monitoring schemes based on existing knowledge rather than on theoretical scenarios based on an extreme interpretation of the precautionary principle leads to the development of entirely new bodies for oversight of monitoring by some member states, and to demands for "monitoring" that have in fact no

relation to the activity as such. For example, in France a body was set up to evaluate monitoring schemes for insect resistant maize after approval was given for commercial production. The bulk of the “monitoring” work proposed was in fact basic research into soil bacterial ecology, not monitoring of insect resistance management.

NOVEL FOOD REGULATION

19. The novel food regulation (97/258) and its dependant directives are the logical complement of the environmental directives on GMOs. Nationally, 97/258 applies to *all novel foods*, regardless of how they are produced, but most of the text, and almost all the public debate surrounding it indicates that it was written essentially for GMO derived food.

20. The EU novel food regulation is based on work of the OECD Group of National Experts on biosafety in biotechnology. This group produced a consensus document based on the notion of substantial equivalence. This notion, well documented in US regulations, was used as the basis for deciding whether a GMO or a derived product should be treated as a novel food or not, and should be subject to additional regulation. When the notion of substantial equivalence was introduced in the EU novel food regulation though, it was given an interpretation that is much narrower than that in the USA. Moreover, different standards have emerged for the determination of equivalence in the debate of safety evaluation (which is the basis for the novel food regulation), and in the debate over labelling.

21. For labelling purposes, substantial equivalence has essentially come to mean chemical identity. Moreover, chemical identity is defined as absence of difference in gene content as determined with state of the art technology. Analytical methodology is an evolving field, and setting a zero tolerance limit in such a situation is always a dangerous regulatory approach. It means that a food producer can be selling food that is non-GMO today, and may with exactly the same ingredients be found working with GMOs tomorrow. The status of food products, especially processed food with relatively long shelf life, may well change between the day they were produced and the day they are tested, not because the food has changed, but because the detection techniques have. This puts food companies in a situation where they face random public outcries about their products that have nothing to do with safety nor with their compliance with the law.

22. The novel food legislation is unenforceable as long as there is no agreement on threshold values. The present situation sets a zero threshold value, and this is technically impossible to police. Modern DNA detection techniques (especially PCR) allow detection of the presence of a foreign gene in a product made with say soybean, even if beans containing that gene are only present in a concentration of one in 10,000.

23. Food is never “pure” by these standards. In practice, the PCR technique gives many “false positives”. For example, transporting non-GMO soybeans in a ship that contained GMO soybeans on its previous shipment will almost certainly give a positive signal in PCR. The dust in the ship (which is mainly composed of fragments of seed hulls) contains enough DNA to show up in such tests as positive.

24. A further complication is that PCR, although extremely sensitive, is not easily quantifiable. If a threshold value—say one per cent—was introduced, PCR is not likely to be able to distinguish between food that contain 0.5 to 1.5 per cent GMO derived material.

25. As long as no threshold values are introduced, and reliable measuring methods agreed upon, the only way for food producers to avoid random scandals about their products is to label almost all their products with the label “may contain GMO products” or some equivalent term. This effectively destroys the basis for the labelling regulation: preservation of the consumer’s right to choose. It has become clear over the past two years that the only practical way to provide consumers with real choice is by the introduction of threshold values, in a way similar to what is done with agrochemicals in organic food.

26. It has recently become clear to many associations of organic farmers that they are themselves not able to comply with present standards to guarantee the GMO free status of their products. This provides an additional push towards the negotiation of a practical threshold value, and an agreed technique for policing the norms.

27. An alternative, which is used in practice now, is to essentially do away with controls, and provide segregated food on the basis of certificates of origin of the raw materials. This is a dangerous situation. A regulation with high exposure to public concern, in which large amounts of material will be categorised purely on the basis of a paper trail, which is not certified by strong policing activities, is an open door to the development of fraud.

28. Finally, threshold values are indispensable for seed certification. Modern seed varieties are sold with an unprecedented level of purity, even before the advent of biotechnology. Depending on the crop certified seed has to be from 95–99 per cent pure (i.e., of the variety mentioned on the package). Seed lots that fail this requirement are rejected. In real life no seed lot is ever 100 per cent pure though, nor need it be. There are technical limits to the seed producer’s capability to keep elite seed separate from other seed lots, while maintaining a reasonable price. But as it is impossible to deliver seed that is guaranteed 100 per cent free from any GMOs, it is by definition impossible to deliver food up to that standard.

THE APPROPRIATENESS AND EFFICACY OF CURRENT LEGISLATION AT THE LEVEL OF THE UNITED KINGDOM AND OTHER MEMBER STATES

29. The United Kingdom and France were the member states that had systems in place for regulatory oversight of research with GMOs before 1980. This is a logical consequence of the longstanding tradition of world class research in the life sciences in these two countries. The introduction of a common regulatory framework for environmental and worker safety by the EU did not present a major problem in these countries, as expert bodies were already in place and functioning.

30. The UK, Denmark and the Netherlands were the only EU member states with a novel food regulation in place before the introduction of the EU directive 97/258. Partly this was the result of British and Dutch frustration with the slow progress made in the development of a common European regulatory framework for novel foods. These three countries have maintained the lead in the evaluation and introduction of novel foods containing GMO derived raw materials.

THE MOST APPROPRIATE JURISDICTIONS FOR DECISIONS ON GENETICALLY MODIFIED ORGANISMS

31. Safety issues related to GMOs fall in two distinct categories: those related to human health, and those related to the environment.

32. Issues related to human health are essentially universal. It would therefore be logical to ensure adoption of common food safety evaluation methods worldwide. In practice the ongoing controversy between the USA and EU about novel food containing GMOs makes it unlikely that such common standards will be reached soon. This has further consequences for international trade. It means that the USA and the EU are at odds with each other over food safety in the international arena. There is an urgent need for the EU and the USA to come to common grounds on food safety issues in general, because in this area it is all too obvious that cultural differences and/or trade considerations are sometimes translated into safety terms to justify different standards. Ideally, food safety standards, with GMOs as well as with other foods, should be the subject of world-wide legislation.

33. Issues related to the environment are more diverse, as the behaviour of organisms is always the result of the interaction between their genetic make-up and the environment in which they develop. However, environmental safety issues related to the introduction of crops do transcend individual countries. The current dominant level of regulation—the EU—seems to be the appropriate one from the scientific point of view. It is also the only one that would not impede the principles of the common market.

THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION.

34. *The seed industry* is hit with high and unpredictable costs. When seed companies introduce their files for approval, they are already upscaling seed production, which is a slow process. If the application files are delayed, a full year's seed may be produced for nothing and has to be destroyed. It is sometimes assumed that such seed can then simply be used elsewhere. This is usually not the case. The varieties developed with a particular gene (eg., insect resistance) are different for different regions, as they should be: their growing environment is different, and they have to be locally adapted. On the other hand, companies can not afford to delay the production of seed until they are absolutely certain of having the permission to sell. This would also delay sales by one or two years, and could destroy any development lead they have spent a large amount of money to build.

35. In the long run this cost is bearable for the seed companies. If the current uncertainties continue to exist for many more years, companies may become more and more reluctant to invest in GMO seed. They will still sell seed to the farmer: the "traditional" varieties sold today.

36. *The hardest hit though is the farming sector.* EU farmers are squeezed between the high cost structure of European farming and the demands to reduce agricultural subsidies. In the long run, the solution has to come from a combination of two factors: reduction of the cost structure, and creation of higher value output. GMO crops are delivering important openings for the achievement of both these objectives.

- The introduction of crops designed to have better pest and disease resistance, and more rational herbicide use, have an immediate impact on production costs for the farmer. The cost reduction is much higher than replacement cost of the agrochemicals saved. Most of the cost of crop protection is not in the products used, but in the investment in equipment and time to apply them to the field. Major cost saving are possible there.
- The introduction of crops with altered output traits is changing several commodity agricultural crops into groups of speciality crops. The best-known European example has been the creation of a potato variety with a specialised starch composition that makes it uniquely suitable as a raw material for the chemical industry (high amylopectin potato). Scientists of the Agricultural University of Wageningen in the Netherlands developed the variety. Such crops automatically command higher prices as they open new market niches. Similar projects are under development (or already

commercialised in the USA) with the vegetable oil composition of major oil crops: oilseed rape and soybean. The attractiveness of these crops lies in the fact that they can prevent several expensive post harvest processing steps, and thereby bring part of the added value that was previously created in the factory back to the farm.

37. An "industry sector" that is often overlooked when considering the impact of legislation on high technology is the "research industry". As our society moves from material to knowledge production as the engine of growth, the research sector becomes an ever more important component of our overall economy. Intellectual inputs can only reach their expected levels of economic impact in terms of national growth if they can be properly protected and valued, and if they can be translated in economic realities in the form of improved goods or services.

38. The first of these requirements has required much more time in the EU than in its major competitors. The EU directive on intellectual property rights for biotechnology has only recently been adopted by the European Parliament, more than 10 years after its initiation.

39. For the second requirement, a stable regulatory environment for R&D is essential. The continuous controversy over GMOs has created great uncertainty among the scientific community about the long-term commitment of the EU to its declared objective of making biotechnology into one of its key development areas over the coming decades. This leads to a brain drain as well as an investment drain. Even today, investment in biotechnology in the EU lags behind our main trading partners. Investment in a knowledge intensive sector like this translates directly into high added value employment. The employment generates the proprietary knowledge that generates new income.

40. Especially the public research institutions are hard hit by the complexity and instability of the regulatory framework, since they often do not have the means to respond timely. The effects of this are creeping, and therefore easily overlooked. They translate into a steady reduction of field agronomic work with GMOs. They can, if continued, also translate in a steady loss of the best brains. Switzerland today offers a severe example of how this can happen. The uncertainty generated by the Swiss referendum on products of biotechnology has made it very difficult for the highly reputed Swiss public research institutes to recruit world class young scientists lately, a situation unheard of until a year ago.

APPENDIX 1

Registration of the first genetically modified maize (Bt-maize) of Novartis Seeds

1. Novartis Seeds AG (former Ciba-Geigy AG) has developed a genetically modified maize, which protects itself against its major pest, the European corn borer. This insect reduces harvest by around 7 per cent worldwide, corresponding to a loss in production of around 20 millions tons of grain. The protection is conferred by the introduction into the maize genome of a gene (called "the Bt gene"), which encodes for an insecticidal protein (called "the Bt protein"). This genetically modified maize will be further referred to as "Bt-maize".

2. In addition to the Bt-maize, Novartis Seeds' genetically modified maize contains two marker genes used as technical aids:

- the "*bla* gene", used during preparation of the material prior to transformation of the plants and which does not confer any particular property to the maize plant; and
- the "*bar* gene", increasing the plant tolerance to phosphinothricin, a herbicidal compound used to identify those plants which have been successfully modified.

3. The registration for commercialization of this Bt-maize began in the United States and in the European Union in 1994, and was followed by similar requests in further countries. Due to the variety of national legislation, even within a given country, several dossiers had to be filed in order to cover the different aspects such as environmental clearance, food clearance and feed clearance. Novartis Seeds always submitted the same basic data package to all agencies, adapting the content to the scope of the request (e.g., environmental data were not included into applications for food clearance) and the form of the presentation according to the local requirements. The following table summarizes the time required to get approval by the various agencies in the various countries:¹

Country	Agency	Duration (months)
USA	USDA	6
	EPA	13
	FDA	5
Canada	Agriculture—Canada	11
	Health—Canada	8

¹ The procedure for hybrid registration is not included in the table, as this procedure exists only in given countries.

Country	Agency	Duration (months)
Japan	Ministry for Agriculture	10
	Ministry for Health	10
Argentina	Ministry for Agriculture	8
Europe	EU—Dir. 90/220/EEC	27
	UK—ACNFP	13
	NL—Ministry for Agriculture	6
	NL—Ministry for Health	12
	DK—Ministry for Health	7
	CH—Ministry for Agriculture	14
	CH—Ministry for Health	14

4. It is obvious from this table that the registration of Bt-maize under the EU Directive 90/220/EEC, took about twice as long as other similar approvals. A history of the regulatory approval of Bt-maize under Directive 90/220/EEC, as well as its analysis from the point of view of the notifier, is presented below.

5. Directive 90/220/EEC requires the notifier to choose a EU Member State to which to submit the application. Novartis Seeds submitted its request to the French Ministry of Agriculture on November 7, 1994. France was chosen because most of the development work for Bt-maize had been conducted in France, and because this country would represent a significant market for Bt-maize. After evaluation by the French biosafety commission (*Commission du Génie Biomoléculaire*), the dossier was transmitted to the EU-Commission at the end of February 1995, and from there to the 14 other EU-Member States, as foreseen by the procedure under Directive 90/220/EEC.

6. Most of the Member States restarted the evaluation procedure already conducted by France, and raised additional questions. Questions continued to be raised even after the official deadline for this had expired (60 days). Two Member States raised formal objections, therefore the dossier had to be referred to the Regulatory Committee under Directive 90/220/EEC ("Committee 21") for vote. The questions and objections focused mainly on:

- the fact that the EU-Regulation on Novel Food was not yet in place at that time. The scope of food safety assessment under Directive 90/220/EEC was not clearly defined and no labelling for food products derived from Bt-maize could be made mandatory;¹
- the articulation on the aspects to be reviewed under Directive 90/220/EEC and under Directive 914/414/EEC for plant protection products; questions on the use and on the metabolism of the herbicidal compounds in Bt-maize were raised;
- insect resistance management: the file discussed extensively the potential for the target insects (the corn borers) to develop resistance against the Bt-protein, outlined the research conducted or to be conducted in this area and the possible ways to address this potential agronomic problem, but in 1994 did not include a formal antiresistance management strategy. During the first years of commercialisation, sufficient non Bt-maize would be available for maintaining susceptible insect populations without selection pressure (unstructured refuges), thus fully allowing time to develop and implement an antiresistance strategy as necessary, based on scientific data and with the full support of the authorities. In addition, it was argued that Directive 90/220/EEC provides only for environmental safety assessment and should therefore not address potential *agronomic* problems;
- the presence of the *bla*-gene in Bt-maize.

As can be seen, most of the objections were of a procedural nature.

7. The submission of the application for formal vote at Committee 21 took nearly one year. During this time, the objections could not be removed despite extensive discussion on the scope of the safety assessment under Directive 90/220/EEC and the submission by Novartis Seeds of extensive documentation (literature data, experimental results, experts' opinion) supporting the safety of the *bla* gene in Bt-maize. The vote took place in April 1996: seven member States accepted the products, four rejected it and four abstained. Because of these abstentions, the qualified majority was not reached and the dossier had to be referred to the Council of Ministers. The Council of Ministers discussed the file in June 1996 but did not come to a conclusion within the allocated time-frame. The EU-Commission therefore submitted the dossier to three EU Scientific Committees (Food, Animal Nutrition and Pesticides), asking them precise questions regarding the safety of Novartis' Bt-maize. These three committees unanimously concluded that Bt-maize was safe for humans and the environment. Based on this conclusion, the EU-Commission "approved" the product on 18 December 1996. This approval was formally granted on 5 February, 1997, by the French authorities.

8. If 5 February, 1997, was an important date for the commercialization of Novartis Seeds Bt-maize in the European Union, it was by no way the end of the procedure. Austria and Luxembourg immediately introduced

¹ Novartis Seeds had already indicated that its product, the seeds of Bt-maize, would be labelled.

safeguard measures against Bt-maize invoking Article 16 of Directive 90/220/EEC. The measures have not yet been withdrawn, despite the opinion of the scientific committees (re-consulted specifically to consider the Austrian objections), of the EU-Commission and of several Member States. The deadline for dealing with such safeguard measures (90 days) have expired long ago. Italy also introduced temporary safeguards measures, but withdrew them in October 1997.

9. In the EU, maize hybrids have to be registered into national/European catalogue in order to be sold. An authorization for the genetic modification under Directive 90/220/EEC is a prerequisite for the registration of each specific hybrid carrying this precise genetic modification. The registration of Novartis Seeds Bt-maize hybrids was delayed until early 1998 in France and Spain because of the transgenic nature of the maize . . . although this "transgenic nature" had been approved in February 1997. Bt-maize was offered to the European farmer for the first time for the 1998 planting season.

10. Grain harvested from Novartis Seeds Bt-maize will enter the food chain. The question of the labelling of the food product has not yet been entirely resolved. As Novartis Bt-maize was placed on the European market before the entry into force of the Novel Food Regulation, food products derived from this maize do not fall within the scope of this Regulation. The EU-Commission issued in September 1997 a Regulation rendering mandatory the labelling of certain food products derived from this maize (Regulation 1813/97). Another Regulation, fixing some rules for this labelling, has just been accepted on 26 May 1998, but the "details" are still not all fixed. The food industry is therefore facing the difficult situation of not knowing how to legally market food products which they have the full right to use.

11. The regulatory pathway for market approval of Novartis Seeds Bt-maize was long and "rocky". The reasons for this are numerous:

- the file submitted by Novartis Seeds under EU Directive 90/220/EEC was the first one to ask for *cultivation and all uses* of a genetically modified plant, whose product would enter the food and feed chains. It was therefore a learning exercise for both regulators and notifiers. By raising concrete questions, Novartis Seeds' application made the authorities aware of the lack of clarity regarding the scope of the risk assessment to be conducted under Directive 90/220/EEC, or under other EU legislation (pending Novel Food Regulation, Directive 91/414/EEC . . .). Different interpretations among the Member States or between the Member States and the Commission often resulted in objections or abstention, which were thus *not* related to the safety of Bt-maize;
- the vote in Committee 21 took place in April 1996. At this time, European regulators and the European media were heavily debating about mad cow disease, new technology, food safety . . . Although scientifically incorrect, an association with gene technology was made;
- the debate in the media and in the political arena increased since 1994 and is still increasing today. The procedural problems encountered by the Novartis Bt-maize dossier were often presented in media as safety issues. The changing position of certain Member States during the review process reflects the impact that the public debate had on the regulatory process;
- the lack of clarity on labelling and the shift in policy from a "safety or ethic-related labelling" (thus only for certain types of genetic modification) to an "information labelling" (applicable to all types of genetic modification) increased the confusion.

12. In conclusion, the registration of Novartis Bt-maize was a pioneering walk in a moving landscape. The European regulatory framework has to become more transparent, predictable and compatible with other regulatory systems worldwide, while maintaining its scientific scrutiny. In the same way as unclear procedures have led to a perception of "unsafe products", it is now time for clear procedures to re-build trust in safe products.

APPENDIX 2

THE LACEWING STORY: EFFECTS OF Bt ON NON-TARGET INSECTS

1. This paper was prepared to react to a widely published allegation that the Bt gene, which is introduced into crops as a source of resistance to some insect pests, also kills useful insects. The allegations stem from research done by a team of scientists from the Swiss Federal Research Station for Agroecology and Agriculture in Zurich, Switzerland under the leadership of Dr Angelika Hilbeck. The subject species of the work was the lacewing *Chrysoperla carnea*, a common predator insect. The results of this work were published in the scientific journal *Environmental Entomology*, volume 27, pages 480–487.

2. The work of Dr Hilbeck is not new. She started work on lacewings and Bt in 1994, and was assisted by Novartis (then Ciba-Geigy) with material of Bt maize. The objective of the study was to find out what happens to a predator insect (in this case the lacewing larva) when it feeds on an insect that has been eating from plants containing Bt genes. The prey species for the lacewings in the study was the European Corn Borer (ECB), which is the target pest of Bt maize, and which is also a common prey for lacewings in the field.

3. From 1995 on, Dr. Hilbeck started circulating the results of her first experiments, alleging that she saw more mortality among lacewings feeding on ECB that had been raised on Bt maize than among lacewings feeding on ECB that had been raised on non-Bt maize. Her conclusion was that the Bt in the maize was affecting

the lacewings. Both company scientists and academic colleagues immediately challenged the results. It was pointed out that ECB larvae <<raised>> on Bt maize were dying or dead by the time the lacewings ate them. The experiment did not take into account that a predator eating dying prey is going to starve by lack of sufficient food, and/or become poisoned by the internally generated toxins in the decomposing prey. The experiment amounts to feeding a dog with rotting meat until he dies.

4. Proper control treatments were suggested, such as powdering healthy ECB larvae with Bt just before feeding them to the lacewings, to distinguish between the insect food effect and the Bt effect. Dr. Hilbeck ignored these suggestions. She repeated the above experiment, but included a parallel trial with another prey insect (*Spodoptera littoralis*, which is less sensitive to Bt). The rationale was that in this second trial, the *S. littoralis* larvae would not be dying and therefore would constitute healthy prey.

5. The result was that again more lacewing larvae died when fed on prey that had eaten Bt plants than on the controls. This led to the conclusion that Bt affects a non-target insect (lacewings), and it was published in *Environmental Entomology*.

6. *We would like to deliver three comments on this paper:*

- (a) An assessment of the experimental work done, and the conclusions reached.
- (b) An assessment of the way in which it was published.
- (c) An assessment of the wider context into which these results, and other evaluations on the effects of Bt are to be seen.

A. THE EXPERIMENTS AND THE CONCLUSIONS

- It is still not understood why the team did not do the obvious control experiment of feeding the lacewing larvae healthy prey powdered with Bt.
- In this study, it was assumed that *Spodoptera Littoralis* was a good control insect, because Dr Hilbeck state that it is insensitive to Bt. It is actually well known that *S Littoralis* is sensitive to Bt albeit less than ECB. It is quite clear why she still chose this insect as a control, instead of using another leaf eating insect prey of the lacewing.
- There have been several other similar studies to investigate possible effects on non-target species. Until now these have come out without showing any effect. Dr Hilbeck mentions some of these studied in passing in the introduction of her paper, but without mentioning which insects were tested. This is significant, because at least two of the studies are about lacewings (Pilcher *et al.*: *Environmental Entomology*; volume 26; pages 446–454; 1997) (Sims *et al.*: *Southwest Entomology*; volume 20, pages 493–500; 1995), and they reach the opposite conclusion of the Hilbeck study. Dr Hilbeck is aware of this, as she mentions the papers in her references, but in her text, she refers to the work of Pilcher and of Sims without mentioning that his work was on the same lacewing. Therefore, she also does not attempt to discuss why she reaches the opposite conclusion of Pilcher or Sims. In scientific publishing, this is unusual. More unusual still is the fact that the referees of the paper have apparently not picked this up and asked her to address this question. It is unlikely that the referees were unaware of Pilcher's work, since it had been published in the same journal as Hilbeck's work, less than one year earlier.
- Dr Hilbeck claims that her work is different from previously published studies in that it tries to study effects of long term feeding. This is correct, but then it obviously becomes crucially important to ensure that the target insects do not die or suffer from the poor health of their prey.
- Dr Hilbeck concludes that the lacewings suffer from a Bt related effect. In a way this is correct. If lacewings are fed during their whole development on prey that is dying or diseased, then they suffer as well. In nature, lacewings are non-specialised predators, eating a wide range of insects. They always have healthy prey to eat, and would likely be totally unaffected by the sick ECB larvae. This is actually the conclusion of field observations of Pilcher *et al.*

B. THE PUBLICATION HISTORY OF THE PAPER

This study has an unusual publication history. Although the experiments were done from 1994 to 1996, it was sent to *Environmental Entomology* on 28 July 1997, and accepted on 25 November 1997. It was published in April 1998.

The results of the paper were widely circulated unofficially after the paper was accepted in November 1997. It was cited and commented upon in *New Scientist* and many other general public media, probably with limited access to the actual paper. From then on, the story of the lacewings started leading its own life, with everyone using it without anyone seeing the actual study. Since the paper itself has only been officially published in April, it is only now that the professional community of entomologists can comment on it.

In the meantime, the “lacewing problem” has become part of the common wisdom on insect resistant crops, and it is highly unlikely that later criticisms on the quality of the study will reach the same audience as the original study did.

C. WIDER CONTEXT OF THE LACEWING RESEARCH

Bt has been fed to a very wide range of insects, both as a spray and through genetically modified plants. The very fact that the only effect ever noticed is in the above study, which can be heavily criticised for its methodology, is an indication that major effects are highly unlikely. It is impossible to prove this, as it is impossible to prove a negative. What is possible though is to compare Bt plants with other practices to control insect pests, and to do a comparative analysis of damage to non-target insects. This has never been done.

Companies develop insect resistance through genetic engineering as an alternative to the use of chemical insecticides. In the furore about the lacewing data, it has been largely overlooked that in the standard treatment of ECB today, most or all lacewings in the field are killed by the treatment. The use of Bt genes is a massive improvement over these older technologies in terms of specificity. Until now nothing indicates that lacewings or any other predator insects suffer from the use of Bt maize. But even if there were to be found a small effect, it is already clear that this effect would always be much less than anything we are doing today for control of insect pests.

Memorandum by the Organisation for Economic Co-operation and Development

1. For the purpose of this evidence, it is necessary to define precisely what are “genetically modified” or “biotechnology” products, since both of these terms (and in particular “biotechnology”) can be used somewhat indiscriminately to describe products developed by a variety of traditional and novel techniques. For the purpose of this evidence, the described work on safety and regulation of biotechnology products is relevant to agricultural products developed using the techniques of recombinant DNA technology.

2. The Member countries decided in 1980 that biotechnology issues should be a part of the OECD work programme. In 1982, “Biotechnology: International Trends and Perspectives” was published. Authored by Professors Alan Bull (University of Canterbury), Geoffrey Holt (The Polytechnic of Central London) and Malcolm Lilly (University College London) this report drew upon the expertise of 14 experts from Europe, Japan and the United States. The report focused primarily on biotechnology (in this case recombinant DNA and other techniques) and micro-organisms, and resulted in a number of recommendations with respect to research and development, training, industry-university links, economic impacts, and patents, and specifically recommended that there was a necessity to study and implement new and pragmatic safety measures.

3. In response to this recommendation, and as requested by the OECD Committee for Scientific and Technological Policy, an *Ad hoc* group of almost 80 national experts (The Group of National Experts on Safety in Biotechnology) made up from 22 of the OECD Member countries, including five from the United Kingdom and seven from the Commission of the European Communities, published “Recombinant DNA Safety Considerations: Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques”. This 1986 report is commonly referred to as “The Blue Book”.

4. In the Blue Book, the group of national experts makes a clear distinction between traditional biotechnologies, such as the use of micro-organisms for wine production and the selection and breeding of agricultural crop plant varieties, and the new techniques using recombinant DNA (more commonly called “genetic engineering”). In the Blue Book, which made the fundamental point that any risks raised by recombinant DNA organisms are expected to be of the same nature as those associated with conventional organisms, are specific recommendations, the first step in the harmonisation process of safety principles and practices among the Member countries of the Organisation. In the early 1980s, consideration focused primarily on recombinant DNA safety in laboratory and industrial fermentation systems, and the 1986 Blue Book made corresponding recommendations on safety criteria for “Good Industrial Large Scale Practices”. With respect to agricultural and environmental applications of recombinant DNA the Blue Book made the following recommendations:

- use the existing considerable data on the environmental and human health effects of living organisms to guide risk assessments;
- ensure that recombinant DNA organisms are evaluated for potential risk prior to applications in agriculture and the environment by means of an independent review of potential risks on a case-by-case basis;
- conduct the development of recombinant DNA organisms for agricultural or environmental applications in a stepwise fashion, moving where appropriate, from the laboratory to the growth chamber and greenhouses, to limited field testing and finally, to large-scale field testing;
- encourage further research to improve the prediction, evaluation and monitoring of the outcome of applications or recombinant DNA organisms.

5. In the Blue Book, the Group of National Experts chose not to consider ethical issues, but rather, paid specific attention to the identification of scientific criteria relevant to the safety assessment and safe use of recombinant DNA products. The publication of the Blue Book was timely as many countries were setting up the regulatory structures considered necessary for notification and assessment of biotechnology products, prior to their proposed introduction into the environment for testing or for commercial use.

6. The OECD Council adopted the "Blue Book" recommendations in 1986, thus expressing a high degree of commitment by Member countries to adopt the common scientific framework set out in report.

7. In 1992 the Group of National Experts published "Safety Considerations for Biotechnology", which elaborated upon the principles set down in the "Blue Book", emphasising Good Industrial Large-Scale Practice for the use of genetically engineered micro-organisms, but more importantly for agricultural purposes, the design of small-scale field research with genetically modified plants and micro-organisms. This was followed in 1993 (77 experts including seven from the United Kingdom) with "Safety Considerations for Biotechnology: Scale-up of Crop Plants", and in 1994 (130 experts including 11 from the United Kingdom) "Safety Considerations for Biotechnology: Scale-up of Micro-organisms as Biofertilizers".

8. These two publications, apart from reaffirming the basic "Blue Book" safety principles in a "Preamble", developed further the principles of safety assessment and environmental safe use of genetically engineered plants and micro-organisms. In particular, the crop plant document, using the concept of "familiarity", explained how existing data on crop plant species development, the novel attribute engineered into the plant, the environment of proposed introduction, and information on crop plant species/environment interactions are all relevant in the case-by-case safety assessment of genetically engineered crop plants.

9. The basic principles having been set out by the Group of National Experts, biotechnology work at the OECD then split into two areas: that of basic and applied research and intellectual property rights, which came under the purview of the Working Party on Biotechnology reporting to the OECD Committee for Scientific and Technology Policy; and plant and micro-organism biosafety which is conducted by the Expert Group on Harmonisation of Regulatory Oversight in Biotechnology, formed in 1994 and which is under the purview of the Joint Meeting of the Chemicals Group and Management Committee, also makes its work available to the OECD Environmental Policy Committee.

10. The first task of the Expert Group on Harmonisation was to survey Member countries on their biotechnology regulatory processes, on the information requirements detailed under those regulations, and on agricultural products that were commercialised. Details of these can be found in Monographs 99, 100 and 107 published in 1995: "Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results"; "Analysis of Information Elements Used in the Assessment of Certain Products of Biotechnology"; and, "Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology" [these publications are enclosed] [not printed].

11. The survey showed that, among the Member countries, the regulation of biotechnology products was the responsibility of a variety of different government agencies, and that their authorities were achieved through new legislation, existing legislation that had been modified or through published guidelines. Nonetheless, Member countries were adhering to the basic safety principles published in the "Blue Book" thus bearing out the commitment made by OECD Council, in 1986, when it adopted the common scientific framework for biotechnology safety. The analysis of information elements required for safety assessment was particularly interesting, as it showed a very great similarity among the Member countries. These surveys show that, at the technical level, there is already considerable harmonisation of biosafety assessment principles among the Member countries.

12. Given the common approach to regulation of biotechnology products among the Member countries, the Expert Group on Harmonisation (which includes delegates from the UK) then developed a work plan that would provide more detailed science on the specific biology of plants and micro-organisms, the specific novel traits being engineered into these, and issues of risk resulting from specific types of modification. These "Consensus Documents" which reiterate the common "Preamble", present scientific data that is mutually recognised by the Member countries, and which is intended to assist in regulatory decision making. In fact, these Consensus Documents may be considered as case-by-case technical descriptions of the components of "familiarity", described in the 1993 "Safety Considerations for Biotechnology: Scale-up of Crop Plants".

13. To date four Consensus Documents have been made available for general distribution: "Consensus Document on General Information Concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection"; "Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Pseudomonas*"; "Consensus Document on the Biology of *Brassica napus* L. (Oilseed rape)"; and, "Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato)". [These publications are enclosed.] [not printed.] The Expert Group has a number of plant and micro-organisms biology consensus documents, as well as specific and general novel trait documents, under development and anticipates their publication for general use on a regular basis.

14. As an outreach activity, the Expert Group makes all of its work available on its Internet site "BioTrack Online" [see enclosed information] [not printed]. This includes links to the regulatory agencies in the Member countries, information on field tests and commercialisation of biotechnology products, and published consensus

documents. This information, which is available to all interested persons, provides transparency to the biotechnology regulatory processes in the Member countries and assists in enabling greater regulatory harmonisation. Also, through its outreach programme, and with the assistance of the United Nations Environment Programme and the United Nations Industry Programme, scientific information from non-member countries that are centres of origin and diversity of crop plant species is available for inclusion in the crop plant species biologies.

15. With respect to point 1(c) in your letter, the OECD member countries have also worked on the safety of novel foods, though not specifically on the issue of whether or how they should be labelled. "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" was published in 1993.

16. This food safety work was undertaken by the Group of National Experts (59 participants including two from the UK and three from the Commission of the European Communities) and is directly related to the 1986 "Blue Book" and the 1992 "Safety Considerations for Biotechnology". The Group of National Experts, recognising benefits to health, nutrition and food preservation resulting from the application of modern biotechnology to food production and processing, elaborated on the scientific principles necessary to assure that the safety of new foods and food components will be at least substantially equivalent to that of widely accepted conventional counterparts. The working group developing the document considered the application of the concept of "substantial equivalence" to be the most practical way to address the issue of food safety. This concept is based on a comparison of a novel food with a traditional food counterpart that has a safe history of use. The publication presents examples of novel food safety assessment through a series of micro-organism, plant, and animal case studies.

17. In 1994, the OECD held a workshop, "Food Safety Evaluation", with collaborative support from the World Health Organisation, in Oxford, UK (52 delegates including 10 from the UK and two from the Commission of the European Communities). This workshop further explored strategies that could be used in establishing the safety of biotechnology derived foods when no conventional counterpart exists for comparison.

18. In 1997 another OECD workshop "The Toxicological and Nutritional Testing of Novel Foods" [report in Press], was held in Aussois, France (in attendance were 64 delegates including three from the Commission of European Communities and seven from the UK). The workshop affirmed the conclusions and recommendations of previous consultations of OECD and of the FAO/WHO regarding the utility of the concept of "substantial equivalence" in establishing the safety of foods and food components derived from genetically modified organisms, and noted that the concept had broader application establishing the safety of novel foods. The 1996 FAO/WHO consultation referred to had concluded, in line with earlier FAO, WHO and OECD recommendations, that the food safety considerations regarding organisms produced by recombinant DNA technology are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding. That consultation also agreed that the comparative approach embodied in the OECD concept of "substantial equivalence" is the basic tool in the assessment used to establish the safety of foods derived from genetically modified plants.

19. As part of an OECD study on regulatory reform, "Uses of Food labelling Regulations, the OECD Report on Regulatory Reform: Volume I", was published in 1997. This study provides an overview of labelling regulations in the context of the food industry as a whole. Where appropriate, particular reference is made to the potential value of labelling regulations in ensuring food safety. I would draw your attention in particular to section V.3.: "Process Attributes: Use of Biotechnology and Environmental Impacts." This publication is submitted for your consideration [*not printed*].

20. Finally, "Biotechnology for Clean Industrial Products and Processes" [in Press], while not directly addressing agricultural biotechnology, states in a chapter on "National and International Policies" that:

- International agreements often serve as a basis for national policies and legislation on clean industrial products and processes.
- Government policy is a major driving force for clean technologies but can have positive or negative effects, so that both of these require careful consideration.
- While many countries consider biotechnology as a critical enabling technology, they have not identified it as a preferred tool for achieving cleaner products and processes; and,
- Policies that affect the marketplace can be most effective in driving change.

Consequently "Government policy, as reflected in regulation, legislation and guidance is recognised as a major driving force behind cleaner technologies, and in many cases and countries, the single most decisive factor in their development and diffusion." The report was developed by an *Ad hoc* task force responsible to the Committee for Scientific and Technological Policy.

Memorandum by the Provision Trade Federation

1. INTRODUCTION

1.1 PTF members are companies of all sizes involved in supplying bacon and ham; chilled and processed meats; dairy products of all kinds, including milk powders, cheese, butter, yogurt and other dairy desserts; and canned foods. Our members include importers and exporters of these products as well as companies who produce

and trade in the UK. The combined turnover of our membership in relation to these products is in the region of £4 billion.

1.2 Those of our members with a current interest in genetic modification are producers and importers of certain meat products and certain dairy desserts which may contain ingredients derived from soya or to a lesser extent, maize, and producers and importers of cheese manufactured using vegetarian chymosin. However, we are conscious that future developments in this field might open up new opportunities for our members. It is therefore important that current legislation should not set precedents which will create barriers to future progress.

1.3 As we represent the trading interests of our members we are not qualified to comment on aspects to do with research and release into the environment of novel foods. Our comments are confined to issues to do with labelling and its regulation.

2. REGULATION OF GENETIC MODIFICATION

2.1 We support the principle of "equivalence" laid down in EC Regulation 258/97 on novel foods and novel food ingredients under which novel foods which are equivalent to conventional products do not need to be labelled. However, the issue has been confused by the subsequent adoption of Council Regulation 1139/98 (compulsory indication of labelling of certain foodstuffs produced from genetically modified organisms) which introduces a stricter interpretation of the meaning of "substantial equivalence". This implies that the presence of protein or DNA from GM material in a product will require the product to be labelled.

2.2 A possible consequence of this measure will be to deter industry from using certain processes or products which might introduce even very small traces of genetically modified material into a final food. This is exemplified by actions being taken by certain companies to replace ingredients originating from soya because the costs of monitoring for, and ensuring the absence of, genetically modified protein or DNA could outweigh the costs of changing to another ingredient which performs the same function and where there is currently no danger of contamination by GM material. If this were to take place on a large scale it could reduce the incentive for the development of new products using GM technology.

2.3 In the case of imports, monitoring GM "contamination" of certain products or ingredients could be necessary in order to provide the importer with a due diligence defence in the event of a challenge by enforcement authorities.

2.4 Another way of avoiding costs of monitoring could be to label all products containing soya derivatives, as it could be argued that it is not possible to guarantee that GM contamination at very low levels will not occur on occasions. It would be unreasonable to expect every batch to be monitored for GM material and labelled only when it is found.

2.5 While some would argue that it might ease the situation by having a threshold within which GM material would not have to be labelled, this could represent a moving target if the occurrence of GM crops increased and made it more difficult to obtain raw material for which there would be confidence that the given threshold will not be exceeded on certain occasions.

11 June 1998

Memorandum by the Royal Netherlands Embassy

GENERAL

1. With a growing number of biotechnology firms and a corresponding number of third-party suppliers geared to serving the industry, the Netherlands boasts a strong setting for biotechnology. In the early 1980s the number of companies undertaking biotechnology activities numbered fewer than ten. Now there are several hundred. Of these, approximately 30 are New Biotechnology Firms (NBFs) operating predominantly in the fields of diagnostics and therapeutics, plant biotechnology and environmental biotechnology. Together, established companies and NBF, which are known for their innovative developments cover all the major areas in which biotechnology is applied, including the agroindustry, chemistry, the food/feed industry, pharmaceuticals, human/veterinary health care and the environment. A further reason for the industry's growth is that the Netherlands' service and supplier base is well-equipped to assist biotechnology companies with a range of activities. Third-party providers and a full range of consultants offer companies product development assistance, the manufacture of batch products for safety testing or clinical trials, and advice on regulatory matters, logistics, marketing and export issues. An effective legal framework guarantees that all modern Dutch biotechnology products have been approved for safety before they are allowed on the market.

2. The five main sectors within the Dutch biotechnology industry all anticipate a major rise in biotechnology-related turnover. By 2010, the share of turnover generated by biotechnology will be largest in the pharmaceutical industry (approximately 30 per cent), but the foodstuffs industry and agricultural sector also anticipate a sharp rise in biotechnology-related turnover, expected to grow from 2–3 per cent in 1996 to almost 20–30 per cent in 2010. This will put them ahead of the environmental and fine chemical sectors, where biotechnology-related turnover still far exceeded that in the agricultural and foodstuffs sectors in 1996. The economic impact of modern biotechnology is expected to be felt most strongly in all four of these sectors. The agri-food sector still only makes limited use of the economic potential of modern biotechnology. Innovation within this sector is a risk-bearing opportunity and consistently produces only small changes. In addition, classic methods still offer sufficient scope for development in the processing and supply industry.

EXPORTS

3. Many Dutch biotechnology firms are export-oriented and are international market leaders. Almost 90 per cent of the Dutch biotechnology companies have one or more permanent bases abroad. Additionally, many leading foreign companies have located their European biotechnology activities in the Netherlands, testifying to the country's excellent biotechnological infrastructure and industrial setting. The main export markets for Dutch biotechnology products are Germany, Spain, France and Belgium.

RESEARCH AND DEVELOPMENT

4. Early investment by the Dutch government has resulted in a well-developed biotechnology research community. The total number of industrial and academic scientists involved in biotechnology in the Netherlands is estimated to be between 3,000 and 4,000. Almost 290 companies in the Netherlands conduct biotech research, involving between 1,500 and 2,000 people. These numbers are expected to increase by 25 per cent over the next few years, particularly in the field of food, agriculture, pharmaceutical applications and the environment. In their research, companies co-operate extensively with universities and research institutes. One of the advanced areas of research in the Netherlands is that of environmental biotechnology. Dutch universities have gathered a large amount of research data on various types of bacteria which can break down pollutants. This knowledge has been successfully developed by one or two environmental companies into reliable high-performance waste-water treatment systems, biological air filters and soil clean-up methods. Further research in environmental technology is currently focusing on the recovery of primary raw materials, in situ treatment methods and process improvements leading to a decrease in by-products, pollutants and waste. The Dutch biotechnology researchers participate actively in the life science subsectors of the European Commission's R&D Framework programme. They are frequently sought as co-ordinators for transnational multidisciplinary co-operation projects, which describes the majority of projects encouraged in these sectors. Industrial biotechnology researchers from Dutch companies are usually among the most active and constructive participants in the European industrial platforms.

EDUCATION

5. The Dutch educational system provides a rich training ground for highly skilled staff in the biotechnology sector. There is a high level of participation in vocational programmes in the Netherlands.

6. Students can sign up for biotechnology courses at 22 centres for higher vocational training. Such courses focus specifically on biotechnology or are part of the regular curricula in industrial technology, environmental technology, medical technology, agricultural technology, bioprocess technology and plant and animal production. The Netherlands is the only country in Europe that offers laboratory training in dedicated higher vocational laboratory schools.

7. Eight Dutch universities offer biotechnology-oriented programmes and extensive training in the disciplines supporting biotechnology, such as biology/chemistry, chemical technology, pharmacy, medicine, veterinary science and food technology.

8. Five biotechnology graduate schools (Centres of Excellence) offer advanced, second-phase biotechnology curricula for post-doctorate and Ph.D students which aim to meet industrial needs and are based on the latest scientific knowledge. Annually they each train approximately 100 Ph.D students and 40 post-graduates.

Sector	Turnover in billions of guilders	Estimated Per cent biotechnology-related turnover		
		1996 Per cent	2000 Per cent	2010 Per cent
Pharmaceutical	4.9	9–10	20–22	34–38
Food/feed	75	3–6	10–12	25–30
Chemical	40	6–13	12–18	20–27
Agriculture	36	2–9	7–18	20–38
Environment	8	4–9	10–15	18–21

FOR FURTHER INFORMATION

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Sources include: NIABA, Ministry of Economic Affairs

May 1997

Memorandum by the Royal Society for the Protection of Birds

INTRODUCTION

We welcome this opportunity to submit evidence to the sub-committee's enquiry into the EU regulation of genetic modification in agriculture.

The RSPB in the UK and Europe (as part of BirdLife International) works towards better understanding of the ecological relationships between species and habitats and land management, and the economics of these activities. We promote constructive ideas for integrating the environment into agriculture policy. We have championed the achievement of specific, measurable and widely accepted targets for biodiversity conservation across farming policy as defined in the Government's Biodiversity Action Plan (BAP).

The RSPB believes that the use of genetically modified (GM) organisms carries the threat of damage to biodiversity. The potential impacts on land-use as a consequence of the utilisation of GM organisms could create big and long term problems for the environment, and in particular for biodiversity. We believe that the current regulatory mechanisms and the way they are interpreted fail to deal with this threat. As a result RSPB have supported the call from English Nature and other UK conservation agencies for a five-year moratorium (until 2002) on allowing GM crops to be grown commercially. During this period we have called for the effects of such crops on the environment and biodiversity to be fully tested. The research should include the impacts on, and the changes in, farming practice and the consequent direct and indirect effects on biodiversity which may occur during or following the use of genetically modified organisms.

HOW DO EXISTING REGULATIONS ADDRESS ENVIRONMENTAL CONCERNS?

1. There are a number of specific concerns that arise from the release of GM organisms into the environment:
 - (a) The establishment of the GMO as a "pest", such that it causes harm to ecological processes or to non-target species within the ecosystem.

- (b) The transfer of the introduced genes from the GMO to other species, which subsequently become established as "pests".
 - (c) Changes in the extent to which herbicides, insecticides and other pesticides are used in the environment.
 - (d) Changes to the range for geographical locations, altitudes, soil types, etc., within which the production of certain crops is economically viable.
 - (e) Changes to seasonal cropping patterns.
2. The existing regulations, both in the UK and Europe appear to have been designed to cover points a and b.
- (a) The establishment of the GMO as a "pest", such that it causes harm to ecological processes or to non-target species within the ecosystem.
 - (b) The transfer of the introduced genes from the GMO to other species, which subsequently become established as "pests".
3. However there appear to be no regulations at EU or UK level that deal with points c, d and e.
- (c) Changes in the extent to which herbicides, insecticides and other pesticides are used in the environment.
 - (d) Changes to the range of geographical locations, altitudes, soil types etc., within which the production of certain crops is economically viable.
 - (e) Changes to seasonal cropping patterns.

We feel that these impacts on land-use, and resulting indirect impacts on biodiversity, as a consequence of the use of GM organisms could create the big and long term problems for the environment. Indeed Professor John Beringer, Chairman of The Advisory Committee on Releases into the Environment (ACRE), alluded to this point in the 1996/7 ACRE Annual Report, Annex 1.

4. As outlined in appendix 1, much of the biodiversity (plants, insects birds and mammals) of farmland has been in decline for at least 25 years. These declines have largely resulted from changes in farming practices resulting from scientific and technological shifts. We believe that the commercial use of GM organisms could lead to further changes and intensification of farming practices adding greater pressure to already declining farmland wildlife.

5. *Example 1: Herbicide tolerant crops.* Such crops are modified to be resistant to "broad spectrum" herbicides, such as glyphosate or glufosinate ammonium. "Broad spectrum" herbicides kill a wide range of plants. In crops which are tolerant to these chemicals all plants and weeds that are not the crop will be removed, whether or not there would be a commercial advantage in doing so. Whilst we recognise that weed control of some form must take place we would question the need to remove all plants that occur in a particular crop.

6. There have been great advances in crop production in the past ten years using integrated systems such as Integrated Crop Management, which aims to reduce environmental impacts of farming within a conventional farming system. The principles of ICM recognises that not all weeds in a crop will have a negative impact on crop yield or performance. ICM systems use thresholds or targeting of specific weed species as an advanced way of dealing with the problem. Herbicide Tolerant Crops go against these principles and could have direct impacts on arable plants that are currently endangered and appear on the Governments BAP such as red hemp nettle and shepherd's needle.

7. There are claims that the amount of herbicide being applied to herbicide tolerant crops will be reduced. This may be true, however it seems highly unlikely that the impacts of herbicide use will be reduced, consequently there is little point in reducing the volume applied.

8. The plants that are removed by "broad-spectrum" chemicals also provide a habitat for insects. Some of these insects are declining in population (see appendix 1), the majority are not pests or crops and indeed some are "beneficial insects" which prey on the insect pests.

9. The loss of plants and insects from the arable ecosystem may have important repercussions for the food chain. A JNCC report, entitled *A Review of the Indirect Effects of Pesticides on Birds* produced by a consortium including, RSPB, Oxford University, BirdLife International, Butterfly Conservation, The Institute of Terrestrial Ecology, and Plantlife was submitted to the Department of the Environment, the Joint Nature Conservation Committee and English Nature in May 1997. The indirect effect of pesticides on birds can be defined as the removal of components thus denying sources of food for birds. The Game Conservancy Trust have shown that indirect effects have caused the decline of the grey partridge (population decline of 82 per cent on the last 25 years). The conclusion of this report found that whilst such effects had not been proven they could not be ruled out for another 19 bird species. The Government has committed itself to conserving 15 of these species in the BAP.

10. The recommendations from this report included calls to try and reduce the impact of pesticide use which could be achieved by encouraging the use of more target-specific chemicals. The use of crops that are genetically

modified to be tolerant to broad spectrum chemicals works in the opposite direction and will have damaging effects on wildlife as a result.

11. The current European regulations fail to pick up these indirect impacts on land-use and consequently on biodiversity. Crops such as glufosinate-ammonium tolerant oilseed rape have already been approved for use and are currently awaiting marketing consent in Member States before they can be grown.

12. An example of the gaps created by the UK regulation is apparent when considering herbicide tolerant crops. ACRE assess the risk to human health and environment according to the type of the herbicide tolerant crop. This would involve the identification of hazards such as capacity to survive, establish and disseminate, potential for gene transfer, phenotypic and geotypic stability, pathogenicity to other organisms. The likelihood of these hazards occurring would then be assessed, followed by an assessment of what this would mean for the environment or for human health.

13. In order to be able to use the herbicide on the crop approval would have to be sought for the new use. Within this assessment would be the efficacy of the chemical at doing the job it is required, and the toxicity of the chemical to humans and certain other species.

14. These two regulatory processes leave a large gap of potentially serious environmental impacts that are not assessed at all in the approval of GM crops.

15. *Example 2: Insect tolerant crops.* Crops that are tolerant to insect attack could be potentially beneficial to wildlife as they could reduce the amount of insecticides being applied to the crop. This could reduce the impact on the food chain by only removing insect pests and not other insects which occur in the field.

16. However a recent report in *New Scientist*¹ looked at research carried out on GM maize that has been modified to be tolerant to an insect, the European corn borer. The work found that there were some secondary effects on an insect predator of the corn borer.

17. The modified crop contains a gene from the bacterium *Bacillus thuringiensis* that produces an insecticidal protein. When the crop pest eats the crop it ingests this "natural" poison. However when an insect predator of the corn borer, the lacewing was fed on corn borer larvae that had been eating the crop, the death-rate of the lacewing doubled. The doubling of death rate was also recorded when lacewings fed on other pests that had been feeding on the crop but were not affected by the poison (the insecticidal protein only affects certain species such as the corn borer).

18. A review of the insects that are food sources for birds, from *The indirect effects of pesticides on birds* shows that lacewing are a dietary component for the 19 bird species, 15 of which appear on the Governments BAP. Therefore the use of this crop could have effects higher up the food chain. Furthermore lacewing are also natural predators of crop pests or "beneficial insects", and can help the farmer in protecting crops.

19. Whilst the lacewing in the wild would not feed exclusively on the corn borer it could have cumulative impacts further down the food chain.

20. This demonstrates again that not all the potentially serious environmental impacts are being covered by the current European regulatory packages. Insect tolerant maize is already commercially grown in the certain parts of Europe.²

21. A further indirect effect of crops that have been modified to resist certain pests or to be resistant to broad-spectrum pesticide use, is that they may remove the need to rotate crops. Crop rotations are traditionally used to reduce impacts of pests (fungal diseases, soil borne insects and weeds). Rotations however are important for wildlife in that they provide a variety of crops in which a greater variety of weeds and insects will exist, consequently providing food for a wider variety of birds and mammals. The loss of rotations could simplify cropping and further reduce habitats and put further pressure on declining wildlife.

APPENDIX 1

(i) *The importance of farmland for wildlife.*

Farmland accounts for approximately 70 per cent of the total land area in the UK. Although highly managed the farmland ecosystem supports a wide variety of wildlife, in many cases it is richer in species than the "natural forest" that it originally replaced. The length of time over which arable farming has occurred has also allowed wildlife to adapt to these new habitats.

A review of bird species in Europe published by BirdLife International in 1994 found that there were 195 species of conservation concern which represents 38 per cent of all European birds (Tucker *et al.* 1994). Of these, 116 utilise lowland farmland for feeding and breeding, and some are highly dependent. In Birds of

¹ *Altered maize kills friend as well as foe, New Scientist*, 2 May 1998.

² It should be noted that it is unlikely that this crop will be grown in the UK due to climatic requirements, however it demonstrates that the regulatory system can fail to pick up impacts on biodiversity.

Conservation Concern the UK's leading non-governmental bird conservation organisations¹ found that of the 36 species of greatest conservation concern 15 depend on lowland farmland habitats².

Farmland is also very important for species of arthropods and plants. Such species are particularly important for birds and mammals as they form the basis for the food chain, for example many farmland birds feed on seeds produced by annual plants that occur in arable and grass fields, or on insects associated with those plants.

(ii) *Declines of wildlife on farmland*

Many of the species that are dependent on arable land have suffered dramatic declines in the past 25 years. The decline of farmland birds has been well documented and the Government has committed itself to conserving the population of 19 species which appear on the UK Biodiversity Action Plan (BAP).

Farmland mammal species, such as brown hare and the pipistrelle bat have also undergone declines and appear in the UK BAP. There have also been serious declines in both numbers and diversity of insects on arable land. The Game Conservancy Trust recorded 4.2 per cent decline per annum between 1972 and 1990, in 700 species of cereal arthropods, and nearly 50 per cent of species of wild bee are considered to be under threat. Species of insect, bee, moth and ground beetles associated with arable land feature in the UK BAP.

Plants of arable land have also dramatically declined in the past 40 years, indeed a few species have become extinct, for example corncockle and thoro-wax. More arable plant species have gone extinct compared to plant species in any other habitat. The plant composition of arable land has also changed with annual grass plants, such as blackgrass and sterile brome, becoming more common over the past 20–30 years, whilst broad-leaved annuals have declined.

(iii) *Causes of declines of farmland wildlife*

Changes in the nature of arable production over the past 30 years, fuelled by the Common Agricultural Policy (CAP) and technological advancement, are thought to have caused these declines. These developments have changed and degraded the environmental aspect of the arable ecosystem and wildlife has not been able to adapt. In particular:

- the loss of over-wintered stubbles;
- the loss of mixed farming;
- the increased use of pesticides and fertilisers.

are thought to be the most significant changes that have resulted in the loss of habitat and breakdown of the food chain.

4 June 1998

Letter from J Sainsbury plc

1. Thank you for inviting J Sainsbury plc to submit evidence as part of the above inquiry. Our largest subsidiary, Sainsbury's Supermarkets, offers over 23,000 products, 40 per cent of which are own brand. Sainsbury's brand products are sourced against our own specifications. Their quality, composition and safety is managed by Sainsbury's 200-strong Technical Division.

2. Sainsbury's position on genetically modified foodstuffs is that set out in the Institute of Grocery Distribution guidelines in March 1997 (Appendix) [not printed]. The IGD Biotechnology Advisory Working Group worked over a period of four years to formulate these guidelines. Sainsbury's Technical Division Departmental Director, Geoff Spriegel, was an active member of it. The IGD guidelines have the support of representatives of just about every link and interested sector of the UK food chain.

3. Sainsbury's policy is that genetically modified foods should be labelled so that customers can make an informed choice about the products they are buying. Adequate labelling is vital to ensure that customers are able to choose whether or not to buy a genetically modified product. In addition to labelling, we also provide customer information leaflets. These are regularly updated and a copy of the latest version is enclosed [see Appendix].

4. In February 1996, Sainsbury's introduced a genetically modified tomato puree. It was clearly labelled "made with genetically modified tomatoes" on the front of the can. Its launch was supported by customer leaflets displayed in store and the company gave a full pre-briefing to the media. The product was introduced with minimum fuss and with maximum consumer acceptance.

¹ Birds of Conservation Concern was produced by RSPB, BirdLife International, Wildfowl and Wetlands Trust, The Game Conservancy Trust, British Trust For Ornithology, The Hawk and Owl Trust, Wildlife Trusts, and The National Trust.

² Grey partridge, quail, stone curlew, turtle dove, skylark, song thrush, spotted flycatcher, red-backed shrike, tree sparrow, linnet, twite, bullfinch, curl bunting, reed bunting and corn bunting.

5. Sainsbury's are able to clearly label the genetically modified tomato puree only because we worked in partnership with the grower and planned for segregation and appropriate labelling. This is the exact opposite to the way in which the genetically modified commodity crops are being introduced to the market and why consumer acceptance of these products is markedly lower.

6. We tried, but unsuccessfully, to persuade Monsanto and the American Soya Bean Association of the need to segregate genetically modified soya from the standard crop for reasons of consumer choice. Subsequently we have worked to source identity preserved soya and soya-protein derivatives for our own brand products. As a result and for the immediate future, we are able to offer fewer products containing genetically modified soya than many other food retailers. We estimate that genetically modified soya is currently used in as few as 30 to 40 of our own brand products. We will continue to source identity preserved soya for as long as supplies remain available.

7. Sainsbury's has confidence in the safety of genetically modified products which have been fully approved for food use in the UK. However, with regard to the regulatory process itself, we have the following comments:

Public Profile of the Approval Bodies

8. It is very clear from the customer letters Sainsbury's receives that the majority of those members of the public who have concerns about genetic modification are unaware of the process through which genetically modified foods have to pass before being approved as safe for sale on the market. They are often unaware of the existence of the Advisory Committee on Releases into the Environment (ACRE) and the Advisory Committee on Novel Foods and Processes (ACNFP) let alone their remit and the effort that is put in to the whole approval process.

9. Even when customers are aware of the approval process, very few seem to know that the minutes of proceedings of ACRE and ACNFP are published and openly available. This apparent lack of transparency and openness creates an impression of having something to hide or, worse still, a belief that the process is uncontrolled.

10. We believe the approval bodies should adopt a higher profile with the aim of helping the general public to take a more informed view of genetic modification. For example we would suggest improving the accessibility of the language style used in minutes and other public documents so that whether or not the readers have technical knowledge, they can comprehend the information published. Another improvement would be the inclusion of details of those foodstuff rejected by the Committee and the reasons why.

Co-ordination between the various approval bodies

11. Each approval body has a specific remit to address approval from a different perspective e.g., food safety, or environmental safety. There appears to be no over arching body responsible for taking a more strategic overview of the foodstuffs being approved and the broader impact their approval might have from an agricultural, environmental and consumer perspective. We believe that the work of the approval bodies should be better co-ordinated to ensure that any gaps that may exist in their responsibilities are identified and addressed.

Public information

12. Approval bodies should be empowered either to require those choosing to bring the technology to market to provide appropriate consumer information about the technology or to run an effective public information campaign. Currently retailers, who have no involvement in the development of the technology nor in the approval of specific products, seek to fill in some of the information gaps for their customers in an attempt to help them to make an informed choice about the products they are buying. All parties have a responsibility to inform consumers and retailers alone should not be looked at to meet this obligation.

Post-Implementation monitoring

13. The EU and UK Government are already looking at introducing regulatory requirements for the monitoring of approved products once introduced to market. We support this approach. In advance of mandatory requirements, approval bodies could play a part in encouraging voluntary measures to be adopted by producers.

14. I hope these comments are helpful. Please let me know if the Committee requires any further information.

Jane Sell

Public Affairs Manager

15 June 1998

APPENDIX

Text of in-store leaflet on genetically modified soya

Genetically modified soya is now being used in greater quantities in UK foods. As a result, Sainsbury's is joining all other UK food retailers and food manufacturers in labelling foods that contain genetically modified soya—even though we are not required by law to do so.

It will state clearly on the packaging if any of our own label products contain ingredients derived from genetically modified soya. This information will be near the ingredients' list and state "Produced from genetically modified soya beans". This will give you the information you need to be able to choose whether or not to buy the product. If this information does not appear on the pack, you can be sure the soya used in the product is non-genetically modified.

Sainsbury's has always said that foods that are genetically modified, or contain genetically modified ingredients, should be clearly labelled to give customers choice.

We have always labelled our genetically modified tomato puree, which we have been selling successfully since January 1996. We were unable to label products that contained genetically modified soya at first. This was because the growers and food manufacturers were not separating genetically modified soya from conventional versions.

Sainsbury's has now made sure that it can trace the source of all soya ingredients used in our own label products. This information has enabled us to label with confidence.

You will, however, find very few own label products that contain genetically modified soya in Sainsbury's. We estimate that genetically modified soya is used in as little as 30 products. Sainsbury's has fewer products containing genetically modified soya than many other food retailers because we have asked our own label suppliers to source non genetically modified soya for as many of our leading lines such as bakery goods, biscuits, cakes and confectionery. No Sainsbury's baby food contains genetically modified Soya.

We made this request so you could have the widest possible choice of food should you wish to avoid genetically modified Soya.

We will continue to keep you informed about developments in genetically modified foods. Sainsbury's believes that each genetically modified whole food or commodity crop should be assessed on its merits.

Soya beans have been used to produce food for many years. They are used in bread and biscuits; sweets; some margarine; baby food and special diet foods. Ingredients made from soya beans—soya flour, soya meal, soya protein and soya lecithin—are valuable and versatile sources of protein and fat.

By law, all food must be safe to eat. The genetically modified Soya bean was assessed by an independent team of UK scientists and specialists, designated by the Government who agreed that the genetically modified Soya bean is as safe to eat as the conventional bean. In addition, regulatory authorities in Europe, Canada and the US also approved the genetically modified bean for use.

Genetically modified Soya plants are produced to be tolerant to an all-purpose weed killer. The weed killer can be sprayed to control all weeds without affecting the Soya plant crop and it also breaks down quickly in the soil.

Memorandum by the Scotch Whisky Association

1. The Scotch Whisky Association welcomes the opportunity to submit written evidence to the enquiry being conducted by Sub-Committee D into genetic modification on agriculture, especially in relation to its regulation by the EC.

2. Of particular concern to the Scotch Whisky Industry is the reaction of consumers to media reports about the availability of consumable products produced from genetically modified (GM) raw materials.

3. As an Industry we are not opposed to genetic modification, properly regulated. However, we do accept the right of consumers to choose whether or not they wish to purchase products made from GM raw materials. Accordingly, we accept the consumers' call for products containing GM materials to be labelled to that effect. Such labelling must relate only to what is in the finished product. We see no requirement for products which do not contain any GM materials to be labelled and we would oppose labelling for products which, although made from GM raw materials, have no such materials or residues thereof in the finished product.

4. There is scientific evidence which indicates that neither protein nor DNA resulting from GM cereals used in the distillation process of Scotch Whisky "carry over" into the new make spirit.

5. However, we are less sure of the position regarding caramel made from GM raw materials. As caramel may be used to standardise the colour of Scotch Whisky released to the market for human consumption, our

members are concerned that unless there is segregation between GM and non-GM raw materials, it will not be possible for them to be able to guarantee that their Scotch Whisky is entirely free of GM material. Accordingly, we encourage the Sub-Committee to conclude that there must be segregation between GM and non-GM raw materials so that end users may be able to give such a guarantee.

6. Segregation will also enable end users to make a choice between using GM raw materials or not.
7. We shall await the outcome of the Sub-Committee's enquiry with much interest.

Memorandum by the Soil Association

INTRODUCTION

The impending introduction of genetically modified organisms into UK agriculture poses the most serious threat ever to the objectives and progress of the organic farming movement in developing and introducing viable systems-based approaches to agriculture.

The issue goes to the heart of what the Soil Association has been endeavouring to achieve for more than 50 years, and brings into focus the directly opposing approach of the organic farming movement and most of the agricultural supply industry towards the sustainability of agricultural production systems.

Even if genetic engineering brings small reduction in the amount of pesticide applied to some individual crops, the whole approach of the genetic engineering industry is to make farmers more, not less reliant on chemical inputs, in particular soluble artificial fertilisers and pesticides. The development of herbicide-resistant crops, for example, will lead to further loss of biodiversity, the "sterilisation" of agricultural crop land and the virtual elimination of food sources for predatory species which can otherwise exist within a cropped area and which can provide a high level of control against agricultural pests. As such the approach is directly opposite to that adopted by organic producers and others using techniques of integrated pest management which have acknowledged benefits for wildlife.

While the techniques of genetic engineering are being used to introduce new genes into agricultural crops it is clear that, due to the selection criteria that are used, the overall trend will be to make farmers reliant on plant varieties which are derived from a substantially smaller genetic base. This will make agriculture as a whole potentially more vulnerable to the development of new pathogenic organisms that may arise in the future.

General Note:

The Soil Association is in general agreement with the submission to the Select Committee made by GeneWatch. To avoid duplication our evidence should be seen as additional to that of GeneWatch.

1. THE APPROPRIATENESS AND EFFICACY OF CURRENT REGULATION OF:

(a) *research*

The Soil Association is concerned that most research on genetically engineered (GE) organisms has been conducted by or on behalf of the biotechnology companies. Very little genuinely independent research into the possible effects of GE organisms has been carried out because the research is viewed as "near market" and most university research faculties are now also financially linked to biotechnology companies. We believe this to be a fundamental problem which the EU is well placed to address. The development of biotechnology in agricultural crop production poses potential major health and environmental problems. In our view it is not sufficient to evaluate research by independent committees, there is a genuine and urgent need for additional independent research. The EU has a European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology which funds work on countering public resistance to biotechnology seen as the biggest problem for the industry. Generous grants are given to support "public understanding".¹

Our experience has been that this promotion *assumes* that biotechnology is the only viable way forward without even considering evidence that shows organic methods offer a viable and safe future for world agriculture.²

(b) *release into the environment*

The release of GE crops poses a specific threat to the integrity of organic production. Legally binding organic farming standards make it clear that genetically modified organisms are not acceptable in organic farming (see Appendix) yet it is already becoming difficult to ensure that organic crops are not "contaminated" by genetically modified material.

We feel it is vital that the regulatory process for licensing genetically modified crops should include an evaluation of the potential impact this may have on organic producers in the area. So far such evaluation has not been undertaken. The potential exists for the transfer of GMOs by cross pollination and other means, such as slow migration of soil bacteria carrying modified DNA, or more rapid transfer by an intermediary such as insects, invertebrates or birds. There is also the potential of continuing reproduction, spread, contamination and hybridisation. This raises questions about the organic status of affected land in addition to organic certification of individual crops.

- In the UK, organic farmers are already deeply concerned about contamination of their crops from the numerous GE test sites around the country. If commercial planting goes ahead as planned, it will be extremely difficult, if not impossible, for organic farming to stay free from contamination due to cross pollination from GE crops and the spread of genes through the micro-organisms in the soil³;
- organic food produced to Soil Association standards is the consumer's only certain guarantee—in the absence of adequate labelling—of GE-free food sources. Infringement of this will affect people's right to choose;
- *Bacillus thuringiensis* (Bt) is a bacterium which has been a cornerstone in sustainable organic agriculture since the 1960s. It is used in occasional applications as an acceptable organic pesticide for serious threats to food crops. Large numbers of crops are now being engineered to express the Bt toxin continuously. Evidence has led the US EPA to predict that these crops could result in resistant pests within 3 to 4 years. The widespread use of GE Bt plants could permanently destroy the effectiveness of Bt against the world's primary agricultural pests and threaten organic farming everywhere.

2. The Soil Association is deeply concerned about so-called *fast track procedures*. These are to be extended and simplified, in particular in the UK. We regard it as imperative that the *opposite* should occur.

- More time should be given to the public to respond (as is their democratic right) to the announcement of an intended release than the current 14 days.
- Any Member State government should be allowed more than the current 90 days for the adequate assessment of any application.

3. The *precautionary principle* should be the guiding light for all releases. Why create a possible hazard where there is no palpable human need? The onus should be on those corporations wishing to release transgenic organisms into the environment to *prove* that no harm will be done. At present, the burden of proof seems to rest with NGOs who are, by comparison to the corporations, almost without resources. GE organisms are released until such time as it is found that unexpected and harmful effects occur—by which time in the case of living and reproducing plants it is too late to do anything. Artificial genomes (and the living beings they code for) can no more be stopped than natural ones and there is real danger of an entirely unintentional epidemic of disease due to unexpected recombination⁴ of viral genes via transgenic hosts.

In view of the gross inadequacies in food safety regulation and the scientific evidence pointing to serious hazards, Drs Mae-Wan Ho and Ricarda Steinbrecher have recommended a number of measures to safeguard the health of consumers and to protect biodiversity. The precautionary principle also demands that a moratorium on further release should be imposed until these measures are implemented:

- (i) No food crops are to be engineered for producing pharmaceuticals and industrial chemicals, as the engineered crops could be mistaken for food, or cross-pollinate with non-engineered food crops. The onus must be on the producer to prove that any plant genetically engineered is not a food crop.
- (ii) All projects involving genetic manipulation of baculovirus for insecticidal purposes should be discontinued, as this virus is being used in human gene therapy and invades human liver cells readily.
- (iii) Complete characterisation of inserted gene sequence(s) of the GE organism (GEO) must be provided in the application for market approval. This should include any antibiotic marker gene(s), promoter(s) and enhancer(s) and their effects on the expression of neighbouring genes. The presence of mobile genetic elements and other proviral sequences in the host genome likely to contribute to secondary mobility of inserts must also be stated.
- (iv) No GEOs with uncharacterised foreign gene inserts are to be considered for release. No parts of such GEOs, nor of animals from failed GE experiments or xenotransplant animals are to be used as human food or animal feed.
- (v) No GEOs containing antibiotic resistant genes are to be considered for release or to be used as human food or animal feed.
- (vi) A detailed record of the stability of the GEO over at least five successive generations of field conditions (including drought and heat) is a precondition for market approval. (Field conditions does not mean open field conditions). This must be supported by appropriate data indicating the stability of the insert as well as the level of gene expression under different conditions in successive generations.
- (vii) Data on the frequency of unintended gene transfers, including horizontal gene transfer from the GEO under field conditions, must be included in application for market approval.

- (viii) Data on the frequency of horizontal gene transfer from GEO to gut bacteria must be included in applications for market approval.
- (ix) Data on the ability of transgenes and marker genes in the GEO to invade mammalian cells must be included in applications for market approval.
- (x) A specified set of tests must be carried out to establish “substantial equivalence”, which are sufficiently discerning to reveal unintended as well as intended effects. The comparator must be the unmodified recipient organism itself, and results of repeated tests must be provided to support the stability of the characteristics over at least five successive generations.
- (xi) Safety assessment must include the GEO’s potential to generate pathogens through genetic recombination.
- (xii) Safety assessment must include pesticide residues where they are integral components of the product, as in herbicide-resistant transgenic plants.
- (xiii) Product segregation, labelling and post-market monitoring are non-negotiable conditions for market approval.

4. The biotechnology corporations have tried to create the impression of a need for GE organisms to “feed the world’s poor”⁵ or create better quality food. To date, the only crops they are attempting to grow commercially in Europe have been those which involve using their particular herbicides⁶ and in which they retain control of seed production. Their claim that the new crops will use less herbicide is disingenuous and indications are that the opposite is true⁷. This will be especially true as Darwinian evolution operates as it always has in the herbicide target plants. They will inevitably develop resistance (just as Colorado potato beetles⁸ have to all insecticides bar Bt and the diamondback moth⁹ already has to GE plants expressing the Bt toxin through its modified genome). This means that farmers will be forced to apply other herbicides to control the resistant crops¹⁰.

5. Many new forms of old diseases (like the various forms of food poisoning in which cases double almost every year) are appearing. Why this is so is uncertain but many scientists suspect a link between overuse of antibiotics in feed and prophylactics in farm animals coupled with new genetic material created in laboratories in and often disposed of into the sewerage system. *Antibiotic resistance* is a desperately serious situation today with the common pathogen *Staphylococcus aureus* resistant, in some strains and in some hospitals, to almost all known antibiotics¹¹. A study in eastern Germany¹² gives an idea of the rapidity with which antibiotic resistance can develop and spread by horizontal gene transfer, and yet persist after antibiotic ceased to be administered. The antibiotic streptothricin was administered to pigs beginning in 1982. By 1983, plasmids encoding streptothricin resistance were found in the pig gut bacteria. This spread to the gut bacteria of farm workers and their family members by 1984 and to the general public and pathological strains of bacteria the following year. The antibiotic was withdrawn in 1990, yet the prevalence of the resistance plasmid has remained high when monitored in 1993 confirming the ability of microbial population to serve as stable reservoirs for replication, recombination and horizontal gene transfer in the absence of selective pressure. Using antibiotic markers in transgenic organisms only hastens the inevitability of further resistance and a return to the pre-penicillin days of septicaemia and a range of other diseases we have almost forgotten about. The transgenic tomatoes currently marketed here and in the US both carry genes for kanamycin resistance. Kanamycin is used to treat TB which is reaching epidemic proportions across the world, the TB bacteria are already resistant to many antibiotics¹³.

6. *Post-release monitoring* of GE crops is not currently carried out. This is a serious omission and the Soil Association strongly urges that a minimum requirement of 10 years should be applied. Negative environmental influences may be subtle or slow to manifest themselves. The observations that “nothing has happened” in the field tests to date are unhelpful. In many cases, adverse impacts are subtle and would almost never be registered when scanning a field. The field tests do not provide a track record of safety but a case of “don’t look, don’t find”¹⁴. The interconnectedness of the complex trophic webs (from soil microbes to large animals) is not even considered by the biotechnology industry, yet the whole biosphere depends on the proper operation of these systems. *Risk assessment* does not take account of the time factor which would enormously increase risk, nor of the cumulative factor.

7. *Horizontal gene transfer*. This issue has been almost totally ignored and yet may turn out to be the most important—and irreversible—effect of the deliberate release of GE organisms into the environment. Similarly, the potential for *cross pollination* has been treated in cavalier fashion by GE proponents. Yet we already know that such pollination can affect weed relatives of the crops¹⁵ and, in particular, nearby non-GE and organic crops¹⁶. We also know that both insect and wind pollination¹⁷ can be effected over considerable distances (at least 8 kilometres) making risible the current regulations for separating GE trial crops from non-GE relatives. Evidence from Dr Peter Kareiva and Dr Ingrid Parker, department of Zoology and botany in the University of Washington in their work, “Environmental risks of genetically engineered organisms and key regulatory issues” stated that “several quantitative analyses of gene flow were undertaken with transgenic plants—while most gene flow clearly does extend to the nearest plants, regardless of the isolation approach, some pollen always seems to move to the distant most sampling stations (Kareiva *et al* 1994 (1), Monasse 1992 (2)). Indeed one of the lessons of ecological genetics over the last decade is that gene flow in plant populations consistently includes

some rare long distance moves of pollen." (Ellstrand 1988 (3), Ellstrand and Hoffman 1990 (4), Klinger *et al* 1992 (5).

8. The conventional process whereby genes move from one plant to another is via pollination. Evidence proves that genes can spread from one crop to another if they are related. The genes are transferred via cross pollination and will also pollinate related weeds, e.g., oil seed rape has been shown to spread to wild relatives through cross pollination of distances over 2.5 km. The threat of cross-pollination is a real one and is taken seriously by the Soil Association and the consumers who buy organic food. Existing regulations do not demand that this type of data be independently investigated *before* any application can be taken into consideration. The Soil Association considers it vital that these aspects are taken seriously with appropriate regulation being enforced, if possible, world-wide.

(c) *Novel foods and their labelling*

1. The Directive should allow individual Member States to *ban the import and use of* a specific GE organism or food on other than scientific grounds if such a ban reflects what the population wish. Numerous opinion polls throughout the EU have shown that a majority of people are deeply concerned about GE and do not wish to consume foods derived from it. It is important to separate other research on and potential of GE for medical purposes which is altogether different from GE foods. If, for example, the British population are to be consulted by plebiscite on whether they approve UK integration into European Monetary Union, how much more important it would be if the population were to be consulted about GE crops and foods. The GE issue has implications as wide for the future as does the EMU. Fundamentally, people elect governments one of whose duties is to ensure the health and welfare of their electorate. People do not elect multinational corporations who are effectively today in control of the food supply (*viz.* the link-up between Monsanto and Cargill¹⁸, the start of a new trend) and, increasingly, dictate to governments what regulatory system (if any) they require, always ready to wield the big stick of threats to employment. It is a truism that "corporations have neither bodies to be punished nor souls to be damned." They, unlike governments, are unaccountable.

2. The principle of *substantial equivalence* (SE) is deeply flawed and unscientific. SE is defined thus: Selected characteristics are compared between the GE product and any variety within the same species. If the two are grossly similar, the GE product will not need to be rigorously tested or labelled on the assumption that it is no more dangerous than the non-GE equivalent. The use of the principle of SE for risk assessment of GE foods—as has been applied by the FAO, the US Food and Drug Authority and the EU—is thus potentially dangerous as it neglects the potential presence in these products of unexpected new molecules. A product could not only be SE, but even be identical with its natural counterpart in all respects bar the presence of a single harmful compound. Indeed, a tame tiger is "substantially equivalent" to a wild tiger. It looks the same and roars the same, but you would only be in danger from the second. Thus SE is irrelevant and useless from a scientific standpoint as a criterion for food safety. The following is a series of objections to substantial equivalence (SE):

- a GE potato, grossly altered, with deformed tubers was nevertheless tested and passed as SE;
 - according to SE, 1-tryptophan¹⁹ that was derived from GE bacteria and implicated in the deaths of 37 people in 1989 contained less than 0.1 per cent of unexpected toxins, would have been regarded as SE and passed as safe for human consumption;
 - there is no scientific alternative to rigorous toxicological testing to ensure satisfactory safety for GE foods as none of these foods currently on the market has undergone testing that is even close to such rigorous assessment required to ensure safety;
 - there is no completely reliable method for identifying unexpected harmful substances, even with the most rigorous safety assessment methodologies available;
- there is no body of existing information upon which to base prediction of unanticipated side effects due to the insertion of a foreign gene into a GE organism.

3. *Labelling*: The Soil Association believes that any product derived from GE organisms should be labelled regardless of whether it is an unprocessed food (like squash or potato) or whether it contains derivatives such as proteins, oils, DNA, sugars, lecithin, starch etc. Trace levels of unexpected toxins could be present in oils refined from GE crops (e.g., rape/canola, sunflower, corn/maize) so labelling should be mandatory if there are any GE derivatives. There are two reasons for this:

- (i) Traceability—if something does go wrong as a result of some specific GE food component and people become ill or die, it is imperative that the toxic agent can be traced back to source so that the source itself can be removed from the food chain. The 1-tryptophan incident (1989, USA) is an example of how important this is since the GE tryptophan was not labelled and, as a result, the epidemic or illness and deaths took months to trace to source.
- (ii) Consumers have a right to know and Europe-wide consumers associations (e.g., Consumers International, the UK Consumers Association) have strongly supported proper labelling of GE. Despite this, their demands were rejected by the UN Codex Alimentarius commission in June 1998. Public perception is such that they do not trust "experts" and scientific-sounding advisory panels and, indeed, their own governments when it comes to fundamentals such as food safety and

wholesomeness. Accordingly, people have a right to know what their food contains so that they may make their own choices about what they, rightly or wrongly, perceive as dangerous. If their governments' advice is not to be trusted, their fallback position is proper labelling. Present EU plans to label GE foods exclude between 95–98 per cent of almost 30,000 products in the supermarkets. A recent *Guardian* survey²⁰ showed that 95 per cent of people in the UK specifically wanted clear labelling of all GE foods *including* derivatives which will not be labelled under current plans. A Citizens' Jury²¹ ruled that GE was unnecessary and could have irreversible consequences. A MORI poll conducted throughout Europe showed that 60 per cent of Europeans were opposed to GE food. Thus EU governments are failing their own people by bowing to the dictates of Codex (an unelected body itself) and the biotechnology industry.

4. THE EFFECT OF REGULATION ON DIFFERENT SECTORS OF THE INDUSTRY AND ON COMPETITION

In May, the EU passed the Directive on the Protection of Biotechnological Inventions. The Soil Association believes that this Directive has been deliberately tailored to the requirements of the biotechnology industry. It will allow patenting of genes, plants (including their seeds) animals, cells, body parts and micro-organisms. This, we believe, flies in the face of the original intention of patents. Now patents on genes extend a huge incentive to the biotechnology industry to create new GE organisms which they can then patent and over which they can then exert monopoly control. Since patents are mostly for 20 years, the companies have a strong incentive to recoup the money they invested as soon as possible regardless of safety or ethical concerns. Accordingly, they may exert pressures on the regulators (i.e., governments) to minimise the testing of GE crops and introduce "fast-track" procedures. Such pressure is compounded by threats of possible job losses if the company fails to get its way.²²

Several simple but vital questions²³ relating to projected food policy and implications of GE still have not been addressed by any governments.

The availability of safe, sustainable, natural methods of breeding and husbandry utilising the many thousand different varieties of any given food crop makes the risks associated with GE foods simply not worth taking. These risks are even less acceptable when one takes into account the fact that once released into the environment, any mistakes cannot be cleaned up or recalled but will be passed on to all future generations indefinitely.

9 June 1998

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¹ For example, the chairman of this group, John Durant, who is also Assistant Director of the Science Museum, has been given £0.5 million to promote biotechnology with a large exhibition mounted by the Science Museum including a woollen jumper made from the wool of Dolly the Sheep. In a public debate with Dr Mae-Wan Ho (debated at the Linnaean Society, Burlington House, London), he denied that he was working to overcome public resistance to genetic engineering. But he did assure the audience that the biotechnology was absolutely safe, so segregation and labelling of GE products was unnecessary.

² Jules Pretty. The Sustainable Intensification of Agriculture. Natural Resources Forum 1997 (UN). Volume 21, No. 4, pp. 247-256.

³ Frank Gebhard and Kornelia Smalla *Transformation of Acinetobacter sp. Strain BD413 by Transgenic Sugar Beet DNA* Appl Environ Microbiol, April 1998, p. 1550-1554, Volume 64, No. 4.

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⁵ Recently, agricultural scientists working in the Philippines announced that they had used sophisticated *traditional* breeding techniques to develop a rice variety that increased the proportion of the plant devoted to rice grains in ways that improved rice yields by 20 per cent, a stunning achievement considering the importance of rice in the human diet (interestingly, the announcement was not accompanied by headlines like "Traditional crop breeding can feed the world") Union of Concerned Scientists. In Latin America, organic growing and fertilisation schemes have tripled or quadrupled yields within one year.

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⁸ *New Scientist Chips are down for killer potato*, 6 April 1995, 9.

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¹⁰ It has been said that "potential development of insect resistance to the Bt toxin cannot be considered an adverse environmental effect as existing agricultural means of controlling such resistant species will still be available". In a similar vein, one could claim that pollution of a river does not matter because there are other rivers available.

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²²“Given the importance of Novartis on the Irish market, (not allowing glyphosate-tolerant sugar beet trials) would have *serious implications for the Irish sugar beet industry*” Affidavit to Irish High Court, section 47d, 1997 by Monsanto Europe.

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APPENDIX

ORGANIC FARMING AND GENETICALLY MODIFIED ORGANISMS

CERTIFICATION OF ORGANIC CROPS

Organic production must take place on clearly defined areas of land which are subject to rigorous inspection and certification by approved Organic Sector Bodies. Organic Sector Bodies are licensed by the United Kingdom Register of Organic Food Standards (UKROFS) which is the UK Certifying Authority under EU Council Regulation (EEC No. 2092/91, as amended). Inspection and certification may also be undertaken directly by UKROFS.

The purpose of inspection and certification procedures is to ensure compliance with organic standards.

In the UK standards for the production of organic crops must comply with EU Council Regulation (EEC No. 2092/91) and with UKROFS standards for Organic Food Production. Approved Organic Sector Bodies may also set additional and/or more rigorous standards. Procedures registered with the Soil Association and licensed to use its organic certification symbol must comply with the Standards for Organic Food and Farming 1987 (as amended).

STANDARDS RELATING TO GENETICALLY MODIFIED ORGANISMS

EU Regulation

Council Regulation (EEC No. 2092/91) is currently being amended to include reference to genetically modified organisms in crop production. This is being undertaken in tandem with the process of including standards for organic livestock production within the EU Regulations. The latest position is set out in the Presidency Draft Working Papers SN 1565/98 (Articles) and SN 1248/98 (the Annex) as most recently amended by Addendum 8697/98. In drafting amendments to the Regulation Council Working Group members have regard to the view of the EU Commission that:

The Commission accepted amendments aiming for a general prohibition of the use of genetically modified organisms and products derived therefrom in the production and processing of organic products.

In relation to the production, advertising and labelling of organic crops and products this general prohibition has been introduced by the following points in the latest Presidency Draft of the supplementing Regulation (EEC No. 2092/91:

9th Recital

Whereas genetically modified organisms (GMOs) and products derived therefrom are not compatible with the organic production methods; whereas, in order to maintain consumer confidence in organic production genetically modified organisms, parts thereof and products derived therefrom must not be used in products labelled as from organic production.

Article 1(2) 2b 12

Genetically modified organism shall mean any organism as defined in Article 2 of the Council Directive (EEC) 220/90 of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

Article 5(3)

The labelling and advertising of a product specified in Article 1(1)(b) may bear indications referring to organic methods in the sales description of the product only where: (h) the product does not contain genetically modified organisms and/or any products derived from such organisms.

Article 5(5)

Products labelled or advertised in accordance with paragraphs 1 or 3 may bear indications referring to conversion to organic production methods, provided that:

(f) The product does not contain genetically modified organisms and/or any products derived from such organisms.

Article 5(5a)

Without prejudice to the provisions of paragraph 3 the labelling and advertising of a product as referred to in Article 1(1)(b) may only bear indications referring to organic production methods where:

(i) The product does not contain genetically modified organisms and/or products derived from such organisms.

Article 6(1)

The organic production method implies that for the purposes of products referred to in Article 1(1)(a) other than seeds and vegetative propagating material:

(d) Genetically modified organisms and products derived from such organisms must not be used.

UNITED KINGDOM

UKROFS standards

II 1.4

The UKROFS board have determined that Genetically Modified Organisms (GMOs) have no place in organic production systems. (For a definition of GMOs in this context see Chapter III, Section 10, Annex IA of UKROFS standards.)

II 4.15

In accordance with the principles of organic production set out in section 1 of this Chapter, plants which have been genetically modified must not be used in organic production.

ANNEX 1A

1. Recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC;
2. Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro injection and micro encapsulation;
3. Cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Memorandum by the Spanish Embassy

In Spain, the two directives regulating the possible risks for the environment (Directive 90/219/EEC and 90/220/EEC) have been incorporated into our domestic legislation by Law 15/94, of the 3 June, which lays down the regulations for contained use, deliberate release and placing on the market of genetically modified organisms, in order to prevent risks to human health and the environment.

The fundamental basis for the procedures set down both in the directives and, logically, in Spanish law, is the Precautionary Principle. That is, bearing in mind that the risks to the environment involved in introducing and handling these organisms are unknown, each operation should be assessed case by case, and following a "step-by-step" procedure to introduce them into the environment.

In Spain, internal negotiation for this programme has been drawn out due to our problems with the political distribution of competences with our regions, so we have been one of the last States to incorporate both directives which have been combined in one single legal instrument. Furthermore, the scope of Directive 90/219/EEC, which only regulated activities with genetically modified micro-organisms, has been extended, just as in most States.

The incorporation of the two directives into the Spanish Law system by means of a regulation of legal status is due firstly to the fact that there exists no General Law on the Environment in our country, nor on Genetic Engineering, so there was no legal capacity which enabled the government to act by means of regulating. Secondly, the risks involved in these activities made it advisable to set down a system of penalties and, in accordance with the Constitution, this may only be done by Law.

In addition to this, the basically regulatory character of both directives made it advisable to incorporate only the basic aspects by Law, leaving detailed questions to be developed by regulation, notwithstanding the possibility for the Autonomous Communities to lay down additional norms.

Last 20 June, Royal Decree 951/1997 was finally passed, approving the general Regulations for the development and Implementation of Law 15/1994. As previously mentioned, these Regulations develop those aspects which are necessary for the effective application of the Law, such as:

1. Requirements for carrying out the activities of contained use and voluntary release of genetically modified organisms.
2. Obligations for the placing on the market of this kind of organism or of products which contain them.
3. Regulations on information, surveillance and control of these activities.
4. Responsibility, infractions and penalties.
5. Creation and competencies of the official Competent Authority for granting state authorization and the National Advisory Body.

The Royal Decree by which the General Regulations are approved for the development and implementation of Law 15/1994 incorporated into internal law not only the provisions of the Directives 90/219/EEC and 90/220/EEC, not included in the Law, but also subsequent Commission Directives passed to adapt their annexes to technical advances:

- Directive 94/51/EEC: criteria for the classification of GMMs in group 1.
- Directive 94/15/EEC: new annex II, differentiating between plants and other GMOs.
- Directive modification of annex III of Dir. 90/220/EEC, incorporating additional provisions on labelling of products which contain or consist of GMOs.

Furthermore, different Commission Decisions are included, which have been passed with the favourable opinion of the Technical Committee, set up under section 21 of both directives:

- Decision 91/448/EEC, modified by 96/134/EC: criteria for determining the risk of GMOs.
- Decision 92/146/EC and 94/211/EC: models to conform to for the information on GMO releases which Member States must send to the Commission.
- Decision 94/730/EC: Simplified Procedures for genetically modified plants.

ANALYSIS OF LAW 15/94

The Law is arranged in the following chapters:

1. General Provisions.
2. Contained use of GMOs.
3. Deliberate release of GMOs.
4. Placing on the market of GMOs or products which contain them.
5. Information and control.
6. Infractions and penalties.
7. Administrative competencies.

One of the most important things is that we, as many other countries in Europe, decided to wide the scope and dealing with organisms for all the activities, and the definition given for an organism includes microorganisms, viruses, viroids; plants and animals; including ova, seeds, pollen, cell cultures and tissue cultures.

CHAPTER II

The first of these activities, contained use, is regulated by chapter II, and is defined as “any activity by which an organism’s genetic material is modified, or by which the modified organism is cultivated, stored, used, transported, destroyed or eliminated, whenever in carrying out these activities physical barriers are used, or a combination of these with chemical or biological barriers, in order to restrict their contact with the population or the environment”.

When the General Law came into force, a data base of institutions working with GMOs in contained facilities was elaborated, resulting that there are more than 200 departments, and around eight laboratories prepared for high risk activities.

Procedures for contained used

	First installations	Teaching, research and development operations	Operations with industrial or commercial objectives
Low-risk GMOs	Communication 3 months	Free of Registry	Communication 2 months
High-risk GMOs	Communication Plus Authorization 3 months	Communication 2 months	Communication plus authorization 3 months

CHAPTER III

Chapter III, relative, as mentioned above, to the deliberate *release of genetically modified organisms for research and development objectives or any other purpose than for placing on the market*, first lays down the concept and scope of application. Thus, release is understood to mean “the deliberate introduction into the environment of an organism or a combination of genetically modified organisms without containment measures having been employed, such as physical barriers or a combination of these with chemical or biological barriers, in order to restrict their contact with the population or the environment”.

When a field release is requested, the competent authority must be presented with:

1. A technical study with all the information and data shown in annex IV of the Regulations, parts A and B, in accordance with the recently-passed modification to this, which consists of laying down different requirements for higher plants (gymnosperms and angiosperms), since experience is much greater than with other organisms.
2. An assessment of the possible effects of the release for human health and the environment.

The application of norms on biosafety in Spain has been carried out in accordance with the indications and principles mentioned at the outset. That is, that these activities must be carried out step by step, from laboratory research to commercial plants, or from laboratory to field, and once their possible effects on human health and the environment have been tested and assessed, the products may be placed on the market.

In addition, it is necessary to assess activities with genetically modified organisms case by case, since the characteristics of different crops and their effects on the environment may vary considerably. Thus, the assessment of new varieties is carried out in accordance with the following criteria:

- characteristics of the donor organism;
- characteristics of the receiving organism;
- sequences introduced;
- environment in which it is released.

In Spain, as mentioned, this assessment is carried out by the Biosafety Commission, our Advisory Body which, since 1991 when the European Directives came into effect, has authorised over 130 field tests, in most cases each one in a variety of places. Prominent among the new varieties tested are those of maize with resistance to herbicides (27 per cent), resistance to insects (14 per cent) or both combined (7 per cent). Maize represents 33 per cent of field releases with respect to the total number of tests carried out. It is followed in second place by tomato (18 per cent), sugarbeet (11 per cent), tobacco (7 per cent) and others in lesser quantities.

CHAPTER IV

The next chapter regulates the placing on the market of genetically modified organisms or products which contain them, which is understood to mean “the delivery to third parties of these organisms or their products”. This delivery is understood to be exclusively commercial. That is, it would not be considered to mean, for example, the delivery by the central office of a multinational company to one of their branches or the depositing of these organisms in order to patent them (article 17).

As regards the report that petitioners must send to the competent authority, the following documentation:

- (a) a technical study with the data and information set down in annex 5 of the Regulations;
- (b) the assessment of risks to human health and the environment, of the product which is to be placed on the market; and
- (c) the conditions for placing on the market as described in the Regulations.

The Spanish authorities have presented three dossiers for placing in the market, that actually have received some objections from other Member States and will pass under the review of The Committee on Plants of the European Commission. The three crops evaluated are:

- Tomato expressing PG activity reduced from the British company Zeneca.
- Bt-Cotton expressing resistance to *Heliothis* from the American company Monsanto, and
- Roundup Ready cotton, expressing tolerance to glyphosate herbicide, from Monsanto as well.

Maize is the most tested crop all over the European Union and in Spain too, it has been the first one (last 23 March, 1998) receiving the grant from the Ministry of Agriculture for the inscription of two varieties which contain the event 176, in the Register of Commercial Varieties.

In view of the requirements of European consumers, after the modification of annex III of Directive 90/220/EEC which came into effect in July, 1997, products commercialized under this directive are obliged to conform to the following type of labelling:

- Mandatory labelling which reads “may contain genetically modified organisms” when it is thought that it may be a combination.
- Mandatory labelling which reads “contains genetically modified organisms” when it is known positively that it does.

In this chapter, it is important to say that last 23 March two GM varieties of Bt-maize containing the event 176 from Novartis have been approved for inclusion in the Spanish Register of Varieties by the Ministry of Agriculture.

CHAPTER V

Chapter V, “Information and control” sets down provisions of a general character which appears in both directives on three aspects of great importance: confidentiality, emergency situations, surveillance and control.

1. As regards confidentiality, article 23 of the Law grants holders the possibility to invoke the confidentiality of certain information and obliges the Administration to take the necessary steps to respect it. Nevertheless, this confidentiality can under no circumstances be applied to the following data:
 - Description of the genetically modified organism.
 - Identity of the holder.
 - Objective and site of activity.
 - Emergency and control measures.
 - Assessment of effects on health and the environment.
2. If the activities regulated give rise to emergency situations, article 24 refers to the legislation on civil protection and special measures on public health issues.
3. As regards surveillance and control (article 25), this will, in all cases, be the responsibility of the Autonomous Communities, to whom holders must offer all their collaboration to achieve it.

CHAPTER VI

One of the aspects which most influenced the incorporation of the two directives by means of a Law was the need to establish possible infractions of the Law and their corresponding penalties, bearing in mind the risks involved in these activities. The Autonomous Communities shall be responsible for enforcing these penalties arising from infractions.

The following, Chapter VI, Infractions and Penalties, lays down the list of infractions, classifying them under slight, serious and very serious. Penalties vary from a fine of 1,000,000 pesetas for slight infractions, up to 100,000,000 pesetas and definite closure of installations for very serious infractions (article 26 and 27). Compensation is also established for damages (article 28) so that, apart from the applicable penalty, those responsible for the infringing activity must return things to their original state and pay those compensations which the court may establish. Criteria laid down for assessing damages are:

- theoretical cost of restitution and replacement;
- value of damaged goods;
- cost of project or activity causing the damage, and
- profits obtained from the infringing activity.

If the action furthermore constitutes an offence, it shall be transferred to the Attorney General's Office and the process of the penalty report shall be suspended.

CHAPTER VII

In Chapter VII, on Administrative Competencies, the Law lays down that both the contained use and the deliberate release of GMOs shall be the responsibility of Autonomous Communities, except in those cases which imply possible incorporation into medicines for human and/or veterinarian use, and in cases of basic state

research (article 31) where the General Administration shall be responsible for granting such authorisation, in addition to cases of commercialisation, where the fifteen Member States give their consent for a product of this type to come onto the market.

The Law lays down that an Official Organisation, under the Ministry of the Environment, in charge of granting those authorisations which correspond to Central Administration, made up from the Ministries of the Environmental Health and Consumption; Agriculture, Fisheries and Food; Industry and Energy and Education and Culture, in which greater significance shall be given to environmental authorities when the activities may imply a risk to the environment, requiring the conformity of Health when dealing with human medicines, and Agriculture when they are veterinarian.

In the final part of the Law there are two additional provisions and seven final provisions, among which the third final provision is especially important, on the creation of the National Biosafety Commission, which shall act as a consultative body for the general Administration and the Autonomous Communities.

Additionally, in the Single Additional Provision for this Royal Decree, the National Biosafety Commission is set up, composed of representatives from the ministries involved (Environment; Health and Consumption; Agriculture, Fisheries and Food; Industry and Energy; Education and Culture, and the Interior), by a representative from the Autonomous Communities that so request and by six experts in representation of institutions related to the issue, where NGO and Trade Unions can be incorporated.

Finally, we should mention the seventh final provision which regulates the preparation, every three years, of a report on the situation in Spain regarding genetically modified organisms (GMOs).

4 June 1998

Memorandum by Unilever plc

ABOUT UNILEVER

1. Unilever is one of the world's largest companies operating in the market for fast moving consumer goods. We manufacture and sell branded products in selected foods, home and personal care categories. We have operations in over 90 countries across the world and sell in over 160. We compete for the favour of the consumer through the long-term appeal of our brands. Their trust in our products relies on their confidence in their performance and quality, and of course their safety in use.

2. Unilever supports the responsible use of modern biotechnology, including genetic modification, within the framework of effective regulatory control and the provision of information about its use. The use of this technology to improve food crops and food products can bring important benefits to society. Individual applications should be judged on their merits. However, these important scientific and industrial developments do raise issues. Unilever advocates effective, clear and properly enforced regulations. We believe that once society has agreed the ground rules setting out the conditions for the application of modern biotechnology, they should be adhered to strictly.

3. As a leading consumer goods company, Unilever is in tune with consumers' needs to have access to information on product contents so that they can make informed choices. An essential component in maintaining public confidence in this technology is the existence of an effective regulatory framework in which consumers can trust.

THE UK AND EU REGULATORY FRAMEWORKS FOR RESEARCH, RELEASE AND NOVEL FOODS

Research

4. The UK was a pioneer in the development and implementation of regulations covering biotechnology, in order to protect workers, public health and the environment. Research involving genetic techniques in laboratories and contained facilities has a history of safe use in the UK, stretching back over the last twenty years. This is due in no small part to the co-operation and contact between scientists and public authorities which has been instrumental in developing appropriate science-based legislation.

5. The UK Advisory Committee on Genetic Modification (and its predecessor, the Genetic Manipulation Advisory Committee) is widely respected for its expertise and competence. Composed of experts from academia and industry, together with public interest representatives, it is a model that has been adopted by many other countries.

6. The European Commission's first legislative initiative in the biotechnology field was at the end of 1978, in order to standardise systems. However, it was not until 1990 that Directives were published which protected workers (90/679) and regulated the contained use of genetically modified organisms (90/219) and their deliberate release (90/220). Unfortunately, this legislation was already out-of-date before it was implemented. In the words of the House of Lords Select Committee on Science and Technology: "In framing the Directives . . . the European Commission took an excessively precautionary line based on a view of the technology which, in terms of scientific knowledge, was already obsolescent when the Directives were being prepared in the late 1980s".

7. Complications were caused by the UK adopting EU Directive 90/219 on the contained use of genetically modified *micro-organisms* in the Genetically Modified Organisms (Contained Use) Regulation 1992. This legislation was never intended for plant materials: contrary to the Commission's intentions for the Directive, this inclusion created an "uneven" playing field in Europe, producing uncertainties and delays in research programmes.

8. Harmonisation of legislation and its implementation across the European Union, and internationally, is essential for public confidence. See paragraphs 13 and 14 below.

Releases

9. As with research, releases into the environment were anticipated by the UK Government and appropriate controls put in place at an early stage. As scientific knowledge and experience has grown these have been successfully incorporated into the statutory risk-assessment procedures. Unilever has had limited experience with release of GMOs into the environment because of the company's limited agricultural research base. The approvals for research releases were executed by the UK's Advisory Committee on Releases (ACRE) in a timely and effective manner.

10. In 1990, the European Commission attempted to create a level playing field for industry with Directive 90/220. However, this created similar problems to Directive 90/219. It has failed to create a level playing field, implementation in member states has been patchy and the delays considerable. This, combined with a continuing difference in perspectives at European level, has had a negative impact on academic research, business and public perception alike.

Novel Foods and their Labelling

11. Unilever recognised the need and supported the proposal for a Novel Food Regulation (NFR) in Europe. The Regulation was finally agreed in May 1997 after nine years. During the discussion period consumer concern has increased because of the perceived lack of control. Although the NFR constitutes a political compromise it is an important step in allowing the developments of modern technology into the market place in a controlled manner.

12. With regard to labelling, the scientific principles articulated in early drafts of the NFR and embodied in the guidelines and those produced by the OECD and FAO have led to a compromise recommendation on labelling in the EU. This, it is to be hoped, will meet the needs of consumers and food manufacturers, such as Unilever, on the provision of information and choice and on a practical and meaningful approach to labelling.

REGULATORY JURISDICTION

13. As global trade increases, business will increasingly be faced with the problems that flow from a lack of harmonisation of regulations relating to the use of genetic modification in agriculture. This has been highlighted recently by the continuing divergence of US and EU regulatory procedures as a result of different approaches to assessments of risk. *Different regulatory regimes also risk undermining public confidence.*

14. Clearly, there is a role for both national regulations and international agreements, as well as industry-wide codes, as the modern biotechnology industry develops. Unilever recognises the value of shared international standards and approaches, both for public confidence and business competitiveness.

THE IMPACT OF REGULATION ON INDUSTRY

15. Different regulatory regimes in different countries inevitably impact on competitiveness. For example, if there is a 90-day period for processing release applications in Europe, compared with 30 days in the US, European companies inevitably face a competitive disadvantage *vis-a-vis* their American counterparts.

16. At the same time, since industrial competitiveness is increasingly built on innovation, and since innovation is as dependent on consumer trust as on technological developments, the effects of non-regulation or inappropriate regulation can have a negative impact on consumer confidence.

17. The challenge is to develop regulatory frameworks which are workable, able to accommodate evolving best practice, as international as possible, and which command consumer confidence. This is an ongoing challenge, and companies and consumers have a shared interest in seeing this kind of regulatory framework properly developed.

11 June 1998

Memorandum by United Biscuits (UK) Limited**UNITED BISCUITS: BACKGROUND**

1. United Biscuits is an international food business operating in 21 countries. It has leading market positions in the UK, Continental Europe and is building its presence in Asia. It has 46 manufacturing sites world-wide and its products are available in over 90 countries. Over 20,000 are employed worldwide of which 16,000 are based in the UK.

Today United Biscuits comprises two main operating divisions: McVitie's Group, the third largest biscuit company in the world and UK Foods Group which together manufacture, market and distribute a wide range of food products.

Brands include household names in all product categories. Some famous brands include McVitie's Digestive, Penguin, and Go Ahead! products, KP Nuts, Hula Hoops and Phileas Fogg snacks. Frozen and Chilled products include Linda McCartney meat-free products, Young's seafood, Ross Chip Shop range and San Marco pizzas. International brands include BN, Verkade, Fazer, and Gyori.

UNITED BISCUITS OVERVIEW OF GENETIC MODIFICATION

2. UB recognises that genetic modification in agriculture could bring many benefits. These are widely acknowledged and include the following: plants with increased pest and disease resistance; reduction in the use of herbicides and pesticides; energy savings in farming; less soil erosion; crops with altered environmental tolerance; and food ingredients modified to improve processing.

3. UB is committed to providing its consumers with products of consistent good quality and value which will appeal to consumers. Furthermore, product safety is an absolute priority. We will therefore use genetically modified ingredients, provided we are confident that they are approved safe and deliver benefit for society. We support the appropriate regulation of genetic modification in agriculture as essential to assure product safety and welcome the opportunity to express our views to the Select Committee on this subject.

4. UB recognises that the proper regulation of genetic modification will play a critical part in addressing consumer concerns, through effective and scientifically based risk procedures. However, we stress that proper regulation alone cannot guarantee consumer acceptance of the new technology. That can only—and must—be achieved through a broader programme of education and information in which government, consumers and all parts of the food chain participate.

RESEARCH*Contained use*

5. The control of research is well regulated in the UK; no significant safety issues have arisen in over 20 years of research and development. In fact the success of the UK system has led to it being used as a template by many other countries.

6. We are aware that many scientists feel that the "Contained Use" regulations are unnecessarily restrictive given the exemplary safety record that exists.

7. Another criticism is that the procedures underpinning the regulations are focused on micro-organisms and are thus inappropriate to the wider applications of genetic modification. This point was made in the 1993 Select Committee on Science and Technology Report on the Regulation of the UK Biotechnology industry and Global Competitiveness.

8. We therefore support initiatives to revise the regulations to adopt a risk-based approach. However, in the current political climate any such changes would need to be presented very carefully to the public; failure to do so is likely to lead to further consumer backlash against the technology.

Release into the environment

9. UB recognises that the system of controls in place is very well established and that the work of the Advisory Committee on Releases into the Environment (ACRE) is highly respected.

10. The European Directive however has led to a number of problems. It has not been implemented consistently throughout the Member States and in practice procedural delays in getting approvals mean that researchers in Europe are at a significant competitive disadvantage compared with those in the US.

11. We support initiatives to simplify the EU system. All procedures implementing the regulations should be transparent and timely. We also support the important role that consumer representatives can play in the decision making process; the EU system should mirror the UK system in this regard.

12. We do not support current demands for a moratorium on field trials. The whole purpose of these trials is to investigate the safety of genetically modified crops and their impact on the environment. Stopping the trials would merely delay answering these vital questions.

13. We are aware of the current debate regarding a proposed seven year monitoring period. Clearly consumer concerns about the safety of the technology cannot be ignored. Any regulations on monitoring should take account, as far as possible, of the need to protect the competitiveness of the UK and European industries. Also, the financial burden should not fall on industry alone.

14. We recognise that some concerns relate to the cumulative effects of different applications of genetic modification in agriculture and that there are calls for an overview to be taken of the broader impact of the technology and its applications. We believe that there is merit in following this line of enquiry, that ACRE is the appropriate body to be given this remit and that its terms of reference should be amended accordingly.

NOVEL FOODS AND THEIR LABELLING

15. As a food manufacturer UB has considerable interest in the regulation of labelling of GM foods. We believe that the provision of information to consumers, including appropriate product labelling, is an essential element in achieving consumer acceptance of genetically modified foods.

16. The fact that comprehensive EU labelling regulations were not agreed before genetically modified soya and maize appeared on the market is a major reason why these products—and indeed the whole principle of genetically modifying foods—have attracted extremely negative media coverage and increasing consumer hostility. The problems caused by the delays in agreeing these regulations, and before them the novel food regulations, should not be underestimated. Delays in implementation of regulations continue, neither a de minimus threshold nor list of exempt ingredients has been established and yet the regulation is to be law from 1 September 1998.

17. We welcome the fact that EU regulations have finally been made on the labelling of GM soya and maize. Whilst these effectively reinterpret the concept of “substantial equivalence” set out in the novel food regulations, and thereby once more apply a different standard for genetically modified foods compared with other novel foods, we recognise that this was a pragmatic solution given the prevailing political environment.

18. The vast majority of UB products including all of McVitie’s biscuits, McVitie’s Prepared Foods and KP snack products do not contain GM soya or maize material which we believe would trigger labelling. However, as stated above (point 16) there remains lack of clarity regarding what the trigger point is. Of the small number of UB products which we believe will trigger labelling under the above rules, most are already being labelled under the voluntary industry guidelines which were agreed in January 1998 in the absence of progress at EU level. We will progressively introduce labelling of the rest by the 1 September deadline.

19. Whilst the EU regulations are an important step forwards it is imperative that the threshold levels for adventitious contamination are agreed and analytical methods developed as a priority so that the regulations can be properly enforced. It should be recognised that as detection methods become increasingly sensitive, threshold levels should not be reduced accordingly.

JURISDICTIONS AND HARMONISATION

20. As already mentioned we believe that both the well established UK system and now the EU regulations satisfactorily ensure the safety of genetically modified organisms. However, in some regards they put Europe at a disadvantage compared with the US and others.

21. Ideally regulation of genetic modification in agriculture should be harmonised at an international level and a risk-based approach should be adopted. This should be achieved through the Codex Alimentarius Commission although the time that body takes to research decisions raises serious questions about its effectiveness.

16 July 1998

Letter from United Nations Industrial Development Organization

I write further to your invitation to provide written evidence to Sub-Committee D, in the course of its enquiry into genetic modification in agriculture, especially with regard to its regulation by the EC. I should make clear at outset that I do not have direct involvement in the implementation of the European Directives governing the environmental release of genetically modified organisms. However, I do have extensive experience of the implementation of regulatory frameworks elsewhere in the world. It is possible that my more general comments, drawing on this broader experience, will provide a useful perspective upon the specificities of European legislation.

1. I draw attention to the need to preserve a degree of national autonomy in the course of implementing frameworks governing the use of genetically modified organisms, without compromising the effort to maintain agreed common denominators within European legislation. This need is reflected in the diversity of national interpretations of Directive 90/220/EEC, as revealed in a recent study (see *An appraisal of the working in practice of directive 90/220/EEC on the deliberate release of Genetically Modified Organisms*, Working Document for the STOA Panel. Luxembourg, January, 1998). It is a need that is confirmed by my experience elsewhere in the world.

2. Whilst harmonisation of biosafety legislation is desirable in the course of promoting free trade, I would point to legitimate differences of national interest which may be compromised in the course of such harmonisation. For example, a concern on the part of some European countries to critically examine the possible impact of transgenic crops in the light of a desire to move towards systems of organic agriculture.

3. In particular, consideration should be given to the further narrowing of the genetic base and a commensurate increase in genetic vulnerability following widespread use of transgenic crops.

4. The impact of transgenic crops upon the long-term use of pesticides and herbicides will also vary from product-to-product, and requires case-specific review.

5. Whilst commercial use of transgenic crops in the EU is as yet inchoate, it is premature to consider a relaxation of the regulatory procedures preceding environmental release of genetically modified organisms. Many of the environmental impacts of transgenic crops may only become apparent after many years' use, and it is important that mechanisms are in place for long-term monitoring of such possible effects.

6. Such relaxation would be particularly inappropriate in view of the widespread public scepticism of the efficacy of the regulation of biotechnology, as revealed in the recent Eurobarometer study.

7. In view of the corresponding public distrust of scientists, who are increasingly perceived as operating to political or industrial agenda, it is evident that there is a need for the strengthening of public involvement in the regulatory process. I suggest that provisions for public information should be strengthened, ultimately to provide for public participation in the regulatory process. Precedents for such public involvement have been set elsewhere in Europe (in Norway, for example). In the long-term, such involvement will benefit the biotechnology industry, through public confidence building.

Please do not hesitate to contact me if you would like me to elaborate further on any of these points.

George T Tzotzos

4 June 1998

Memorandum by Dr phil. ir. René von Schomberg

1. DEFINING PRECAUTION

An international agreement on the precautionary principle was reached during the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro 1992 and became part of Agenda 21. Since then the precautionary principle has been mainly discussed in two areas of international environmental policy, e.g., global climate change and biodiversity conservation/biotechnology regulation. National governments have also discussed and implemented the precautionary principle in other areas such as the emission of chemical waste or areas for (nuclear) waste disposal. The precautionary principle is also inscribed in the EC Treaty (article 130R).

In the framework of Agenda 21, the precautionary principle has two basic characteristics. This note is based on this interpretation of such a precautionary principle.

1. The principle is to be applied in cases of potential irreversible impacts on the environment with relative high consequences (implying that these consequences are unacceptable).

2. Governmental action should be taken without the availability of complete scientific evidence. These circumstances are referred to as instances of scientific uncertainty. Scientific uncertainties arise because of controversies over the possibility or the scope of environmental effects caused by human (technological) interventions.

It is important to note that the precautionary principle is a formal principle which implies that, depending on the area to which it would be applied, it could result in quite different types of environmental policies or regulation.

2. IMPLEMENTING THE PRECAUTIONARY PRINCIPLE IN EUROPEAN BIOTECHNOLOGY REGULATION

The European Directive 90/220/EC concerning the deliberate release of genetically modified organisms (GMOs) into the environment is the first piece of international legislation in which the precautionary principle is translated into precautionary regulation. There is no experimental scientific evidence for harm to humans or

the environment caused by GMOs but ecologists consider it plausible that single releases of GMOs could cause for instance irreversible effects on the natural vegetation (decrease of biodiversity) or resistant weeds. There is scientific uncertainty whether GMOs pose an additional risk in comparison to conventional cultivation methods. In the framework of this directive the precautionary principle is formalised by a so-called *case by case* and a *step by step* procedure. The case by case procedure facilitates a (in most cases) mandatory scientific evaluation by Member States of every single release of a GMO. The step by step procedure facilitates a progressive line of development of GMO's by evaluating the environmental impacts of releases in decreasing steps of physical/biological containment (from greenhouse experiments, to small scale and large scale fields tests up to market approval). This procedural implementation of the precautionary principle implies an ongoing scientific evaluation and identification of possible risks. The procedure also results in the accumulation of scientific data which provides input to new evaluations.

3. MAIN FEATURES OF PRECAUTIONARY REGULATION

3.1 *Flexible standards*

Precautionary regulation always implies the regulation of a subject matter on the basis of standards that remain open for discussion. The regulation itself cannot define these standards. This is a completely new dimension in international environmental policy and not always appreciated. Directive 90/220, for instance, also leaves open what precisely can be considered as an "adverse effect on human health and the environment". The directive also leaves open what could be a sufficient demonstration of safety. The combination of a case by case evaluation and the absence of fixed standards for evaluating these cases provide the background for ongoing deliberations at national level and in scientific advisory committees. Instead of fixed standards, individual Member States use flexible standards to define the acceptability of releases. "Reduction of biodiversity" or "comparison with the risks of conventional agricultural practices" are examples of such standards. These standards do also not predefine the outcome of the evaluation of scientific advisory committees. Depending on the availability of scientific evidence and the location of releases of GMO's the evaluation on the basis of such a standard may differ over time. You could therefore call these standards "flexible". The state of the art in science is concerning the knowledge of natural processes also determines the outcome of evaluations in the light of these standards. For instance the environmental effect of transfer of genes from GMOs to wild relatives may either be perceived as "genetic pollution" or as a natural (= acceptable) process depending on our knowledge whether such a gene transfer would take place under natural circumstances. The standards to be applied can therefore transform previously defined unacceptable releases into acceptable releases if studies of natural processes provide us with a new understanding. Disagreements between Member States relate to the application of these standards whereas there is hardly any disagreement on the probability of major environmental effects (Von Schomberg, 1998).

3.2 *Proportionate regulatory requirements*

Precautionary regulation is by definition (Agenda 21) a regulation, which cannot be based on a complete cost-benefit analysis. The scientific uncertainties concerning the subject matter do not make such an analysis possible. Precautionary regulation is constrained to cases in which it is plausible that irreversible environmental consequences are involved which are (internationally) predefined as unacceptable. Precautionary action does not relate directly to demonstrated actual risk but to anticipated plausible risks.

However, a general cost-benefit analysis could precede a political multilateral decision whether or not to translate the precautionary principle into proportionate regulatory requirements. For that purpose three points can be evaluated in proportionate relation to each other:

- (1) An assessment of the scope of the scientific uncertainties and the scope of possible environmental effects.
- (2) The costs and benefits for maintaining the status quo.
- (3) The costs and benefits for changing the status quo. The precautionary principle can be used to maintain or reverse the status quo.

Such a general analysis also remains important after the decision to implement precautionary regulation on a particular subject since the accumulation of scientific evidence during the time frame of such a regulation could make it appropriate to reconsider the scope of precautionary measures. The acknowledgement of the precautionary principle thus implies the evaluation of the scope of the measures to be taken and when they should be taken.

The scientific uncertainties concerning the subject matter also imply the impossibility of a full quantitative risk assessment whenever the precautionary regulation is implemented. It is, however, possible to implement a precautionary regulation which is commensurate with the identified uncertainties or risks involved. Directive 90/220 is an potential example of proportionate regulatory requirements. The regulations facilitate ongoing revisions of the standards of risk assessment to be used. This means that these standards could be relaxed or strengthened over time depending on the accumulation of scientific evidence. It is very important to note that

precautionary regulation can never be aimed at a categorical ban on products or experiments. In the context of incomplete scientific knowledge, it is even necessary to gain practical experience with products or experiments in order to complete scientific knowledge and for identifying actual risks. The accumulation of scientific insight by precautionary use enables the update of standards for risk assessments. Thus precautionary regulation can facilitate guided introduction on the market of particular products.

Post-market technology assessments and monitoring of products/technologies by industry could complement a precautionary regulation and would provide the necessary feedback for such a regulation.

4. TRADE ASPECTS OF PRECAUTIONARY REGULATION

4.1 *Internal market*

The Maastricht Treaty allows individual Member States to take all “appropriate measures to avoid adverse effects on human health and the environment”. However, this statement in the EC Treaty may be linked to other statements concerning the internal market in specific EC directives or regulations, such as is the case of the Directive concerning the deliberate release of genetically modified organisms into the environment (EC 90/220). The new Amsterdam Treaty remains ambiguous on this point. The Amsterdam Treaty allows an individual Member State to apply stricter environmental measures than those provided by European legislation in so far as the country does thereby not impose trade barriers. Only a ruling by the European Court of Justice could clarify what this will mean in cases where precautionary regulation is linked to an obligation of the internal market.

However, from a policy point of view, it would be consistent to complement precautionary regulation with a European policy that allows for flexible trade barriers. Precautionary regulation always needs ongoing deliberation at national level which inevitably will cause divergent ideas about the acceptability of uncertainties. If we wish to respect these differences we have to accept flexible trade barriers as we do accept flexible standards for assessing uncertainties. These trade “barriers” would then be restricted to the areas for which we wish to implement precautionary regulation.

European biotechnology regulation has indeed resulted in the use of different standards by different countries which has indeed become the case in the framework of Directive 90/220. Austria and Luxembourg have imposed a ban on EC approved products and the European Council has repeatedly postponed a European Commission proposal to enforce a lifting of these bans. These conflicts among Member States reflect an inadequate understanding of the meaning of precautionary regulation since such regulation cannot be scientifically aimed at a zero-risk level. Therefore, it is not appropriate to reverse the burden of proof and call for demonstrated proof of safety instead of a demonstration of actual risks in case for case assessments. In fact, precautionary regulation has been implemented to postpone a burden of proof both on the side who claim the plausibility of adverse effects and those who claim plausibility of sufficient safety.

5.1 *General conclusions for Policy Options for the revision of directive 90/220/EEC*

Since the laborious process of the implementation of the directive (in 1992 only four countries managed to implement the directive) within obligatory 18 months time frame work (UK, NL, DK and D) Luxembourg implemented the directive as the last country early 1997; no country has been brought for the European Court of Justice for not implementing the directive) the policy and societal discussion on the release of GMOs have shifted to the meaningful implementation of a precautionary practice in the context of member states. Despite all the controversies, no political actor, organisation or member state has questioned the necessity of a precautionary approach. Now we stand before a revision of the directive, all major parties involved in the policy process, such as national competent authorities, Bioindustry and NGOs has reaffirmed the precautionary approach (Von Schombert, 1998). The precautionary principle has been formalized in the procedure by a case for case and step for step approach. Differences between Member States, arise in how far this formal procedure has been materialized in the Member State in the absence of pre-given definitions for environmental harm and risk, but most importantly in the absence of harmonized standards for what would count as (un)acceptable environmental or health effects.

Precautionary regulation facilitates:

1. An ongoing basis scientific deliberation within the policy context—this means a shift in science based policy as presupposed to be possible by the current directive towards a scientific debate on uncertainties within the policy context: this means decision should not only be based on available data but also on plausible notions of what could be the case.
2. An ongoing discussion on transformable/flexible standards within the regulatory framework but also in the societal context of this regulatory framework.
3. The awareness of the need of monitoring and continuous interest in the experience with releases and market product.

4. The awareness for the need for a long-term perspective, which is implemented by a precautionary and flexible practice.

All member states and the major interest groups embrace a precautionary approach. Therefore only minor changes of the current directive in so far the directive serves as a safety net are acceptable. The most prevailing problem resulting from the Europawide acceptance of the precautionary approach is that this can only be practised by a continuous deliberation on flexible standards. These discussions materialize differently in the different member states. From this state of affairs arises the problem whether it is a legitimate way of acting to impose decisions on countries in which this process of deliberation deviates from other countries.

5.2 *Conclusion on recent proposals of the European Commission to modify directive 90/220*

Across the member states and among experts of advisory committees, disagreements arose on the application of the standards of risk assessments rather than on the plausibility of environmental harm which can be caused by releases of genetically modified organisms. To achieve a consensus among experts in advisory committees as well as among the competent authorities of the Member States a clarification is needed on how to review releases in the light of one of the following standards which determine the outcome of risk assessments and the decision of competent authorities.

- conventional agricultural practice;
- biodiversity;
- sustainable development;
- agronomic effects.

This report shows that these standards have been used by the Member States, thereby creating dissent among experts and among competent authorities. An open discussion of these standards was hindered by the dominant interpretation of the directive that only allows for an assessment of the scientific-technical safety aspects of releases. However, the working in practice of the directive has shown that the application and choice for a standard is necessary in order to substantiate a claim for the acceptability of individual releases and market products. The standard of "conventional agricultural practice" is a too small basis for a precautionary approach and belongs to the option of those who would favour a product-legislation. To envision the directive as a precautionary safety net, would favour the option to focus on safety/biodiversity (which already has a consensus in the European Union through the biodiversity declarations on the 1992 UNCED conference in Rio de Janeiro). H Martin of the European Commission confirmed in an interview that this would be a possible policy, but disagreements might remain since biodiversity is interpreted differently by some member states through the application of different thresholds for effects on biodiversity. Sustainable development and agronomic effects are standards which are likely not to achieve a consensual basis among the member states. These standards reflect a more integrative approach to environmental issues but are difficult to apply within the specific context of a process-based legislation. The European Commission is not willing to consider these standards for amending the directive.

The European Commission announced in its communication of December, 1996 on the review of directive 90/220/EEC (COM(96)630) to come with a proposal to amend this directive, which concerns the deliberate release of genetically modified organisms, during 1997. The Commission has made such an proposal in November 1997 (Proposal for a Directive of the European Parliament and of the Council amending Council Directive on the deliberate release into the environment of genetically modified organisms).

Member States have interpreted the current directive differently and this directive did not foresee in a procedure to resolve these disagreements. Scientific risk assessments could not enforce a consensus on the risks of genetically modified organisms (GMOs). The approval of market-products has been delayed in almost all cases. Proposals to amend the directive has come from competent authorities of the member states, industrial organisations and non-governmental organisations. Below I will summarize the most significant proposals of the European Commission.

The Commission has proposed to amend the directive with the implementation of a risk management strategy. It remains unclear how such a strategy could be implemented without using standards which are derived from current agricultural practices. Without defining a standard, a contradiction will be created in the implementation of the directive, since at the moment an appeal to agronomical effects are not accepted.

However, the recent acceptance of the Italian CA to lift the ban on the modified Maize, after an agreement with Novartis to conduct monitoring experiments with such a maize, is an important policy-precedent of how to combine acceptability with management strategies.

The instalment of an independent Risk Assessment Committee on European Level is anticipated to surpass the advisory committees of the national member states. However, disagreement will also appear in such a committee if no clear agreement is achieved on the application of definitions of acceptability. Some member state could be encouraged to use article 16, to ban certain products, if they feel excluded in the deliberations on these standards.

The Commission has now proposed to amend the directive, concerning article 16, by restricting the use of this article to those cases when *during the approval procedure* new information has become available which would make a reconsideration necessary. This proposal does not reflect the essence of a precautionary approach in which the *lack* of such information could be a reasonable ground to reconsider a case. The Commission seems to reject any proposal for a qualitative "risk" assessment. This constitutes a major conflict with environmental and consumer organisations and makes negotiations with these organisations very difficult.

The development of policy by competent authorities of the member states has moved from Risk-based regulation to Uncertainty-based regulation. There is a growing awareness that the issue of deliberate release has to be seen in the context of an uncertainty-based regulation which is characterized, among others, by the application of deliberations-based standards of risk assessment. In our analysis, this is adequate for the current situation. A precautionary approach is determined by both the absence of a definition of environmental harm and an ongoing acquisition of scientific knowledge which may change the acceptability of individual releases over time. Therefore an ongoing discussion among experts of scientific advisory committees as well as among competent authorities of member states is unavoidable and necessary to cope with uncertainties and define the meaning of standards of risk assessment in concrete cases. Therefore, the interaction between member states and advisory committees should be encouraged rather than abolished: for effective decision making, administrative procedures should be facilitated to make decision possible within a certain frame, but also the possibility of the reversibility of decisions should be considered. Countries might have less problems with certain products or releases if they are confirmed that these decisions can be reversed once environmental harm could be demonstrated. It is therefore a significant step that the Commission proposes to link the market consents with mandatory monitoring strategies.

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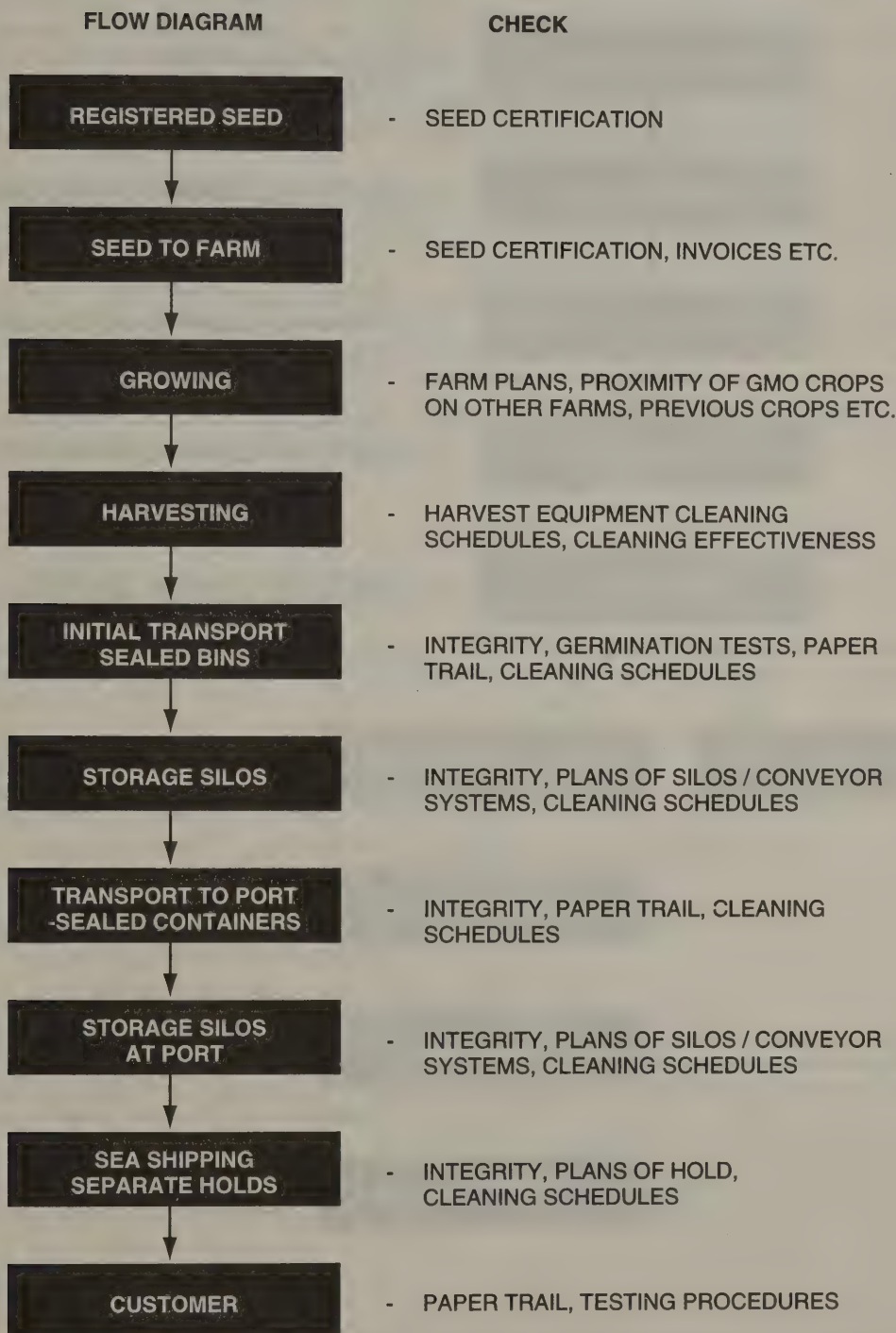
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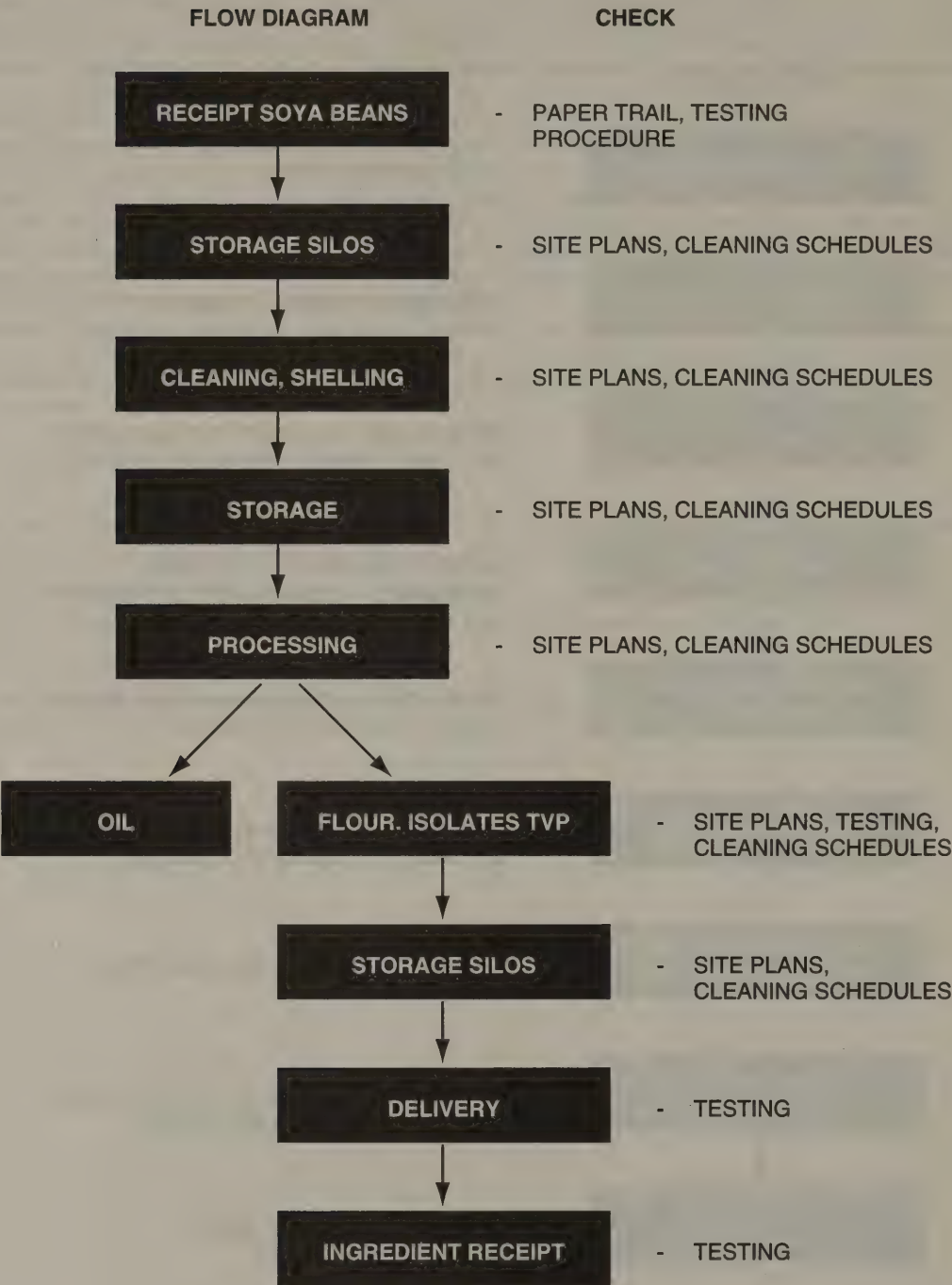
Acknowledgements:

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Supplementary Memorandum by United Biscuits (UK) Limited

TRACEABILITY FLOW CHART - NON GMO SOYA BEANS
PLANTING, HARVESTING, SHIPPING

TRACEABILITY FLOW CHART - NON GMO SOYA BEANS
MILLING PROCESSING, DELIVERY



Further Supplementary Memorandum by United Biscuits (UK) Limited

INTRODUCTION

United Biscuits (UB) has already provided significant input to the Committee.

In July 1998, the company presented a written submission detailing its views relating to the important issue of genetic modification (GM) in agriculture.

Subsequently, on October 14, 1998, at the request of the Committee, the company attended a meeting of the Committee to answer a series of questions put by Members.

During that presentation, Lord Jopling was particularly interested in the consultation undertaken with food manufacturers by bio-sciences companies prior to the introduction of advances such as the genetic modification of crops.

UB indicated its support of bio-sciences companies in the development of this technology, however, it did object strongly when advances were imposed without due consultation and the opportunity for a reasonable period of scientific review.

UB pointed out that it felt its views had been “trampled upon” by the fact that its opinions had not been sought in advance of introduction of co-mingled GM crop to the UK and Continental Europe. This phrase was not meant to convey an accusation of systematic cavalier treatment by bio-sciences companies, so much as a cry of frustration over the way in which these particular GM crops were introduced.

Lord Jopling asked that UB consider providing additional details in respect of the lack of consultation and this supplementary submission is UB’s considered response to that request.

THE LACK OF CONSULTATION

As was pointed out in our October 14 presentation, consumer anxiety arises when food manufacturers have insufficient time to consider new developments and to plan their introduction.

This is always true, but it is especially important when there are aspects of advances which are potentially controversial or which, through lack of information, can tend to cause anxiety among our customers and consumers.

Moreover, as was indicated by us, the “forge-ahead-at-all-costs” approach invariably results in increased costs for manufacturers.

This has certainly proven to be the case for United Biscuits as the company has:

- despatched buyers to many parts of the world to source traditional/traceable crops;
- paid a premium for traceable/traditional crops;
- met the costs of extensive additional testing of crops and final products;
- incurred significant additional labelling costs;
- devoted much time of many senior executives to the issue.

Additionally, this approach works against providing consumers with choice if manufacturers through no fault of their own, cannot meet customer expectation. Despite strenuous efforts to source traceable traditional crop—only to find that there is trace presence of GM material, the dilemma is clearly whether or not to label. If the approach is to label, this would result in blanket labelling and offer consumers no choice.

Due consultation *before* the introduction of these new crops would have resulted, UB believes, in less consumer anxiety, less expense and consumer choice. The process of introduction could, and should, have been handled more slowly so as to generate greater confidence and more ready acceptance.

THE FUTURE

While this has been a frustrating and unsatisfactory period UB believes that there can be a positive outcome if lessons are learnt.

In future, United Biscuits would like to see:

- A period of consultation with all relevant parties—prior to commercialisation of GM in the case of crops or marketing of the product.
- An opportunity to review existing science and to influence new research to underpin the introduction of GM foods during the above consultation period.

- Communication of consumer benefits flowing from the new advance.
- Traceability, if needed, is confirmed.
- All regulatory issues in Europe, including labelling, must be clear, before commercialisation of GM materials.
- Greater clarity of principle and setting of threshold levels, where appropriate.
- Scientifically accurate and up to date information to be developed and a communication programme informing consumers, opinion formers and the media to be undertaken in advance of introduction of GM materials.

It is United Biscuits' view that if a more orderly and patient approach were adopted, the likelihood of consumer acceptance would be maximised and food manufacturers would not be placed in the difficult position of having to go to considerable expense and effort in order to supply their customers and consumers in the way they wish.

UB supports the Government's announcement to establish a new Ministerial Group which will oversee strict monitoring of first commercial plantings of GM crops. Managed development of GM crops prior to commercialisation, will we believe help allay concerns and ensure that advances in the technology can continue, but with adequate scientific assessment and evaluation.

SUMMARY

United Biscuits welcomes the Committee's enquiry into this important topic.

The company believes that, in the long term, there are likely to be benefits to society as a whole and to individual consumers, from the introduction of genetically modified foods.

However, because any changes in the supply chain, or the introduction of bio-tech advances impact strongly on the operations of food manufacturers, we believe their views are most relevant and prior consultation must take place.

Companies like United Biscuits can do much to ease the introduction of new advances in food by working with the broader industry to devise and implement information programmes, by monitoring consumer attitudes, by working with Governments to effect workable regulations and, ultimately, to deliver a better product to customers and consumers alike.

UB commends the Committee for its deliberations.

28 October 1998

Supplementary Memorandum by the Food and Drink Federation

FACTS AND FIGURES—TRANSGENIC CROPS

Global area of transgenic crops (ex China) in M hectares

1995	—	0
1996	—	2
1997	—	11
1998	—	28 of which 20 M in USA (rest comprise nine countries)

Crop	M Hectares	1998	
		Per cent transgenic of total (not of crop)	
Soybeans	14.5	52	
Corn	8.3	24	
Cotton	2.5	9	
Canola	2.4	9	
Potato	<0.1	6	(20,000 hectares, Bt, Yvirus, Pot leaf role)

- 20,000 hectares of Bt maize have been grown in Spain
- 2,000 hectares of Bt maize have been grown in France
- 15,900 tonnes of maize were imported into Spain from the 1997 US harvest

Canada: Main crop is Canola

Mexico

Total 117 field trials

Corn	38
Tomato	23
Cotton	17
Soybean	9
Squash	6
Potato	5
Papaya	4

Deregulated Status—Mexico

Tomato—Calgene (FlavrSavr)

Zeneca

Soybean Oil—Modification

Potato—Bt

To date worldwide:

25,000 field trials

60 crops

45 countries

Monsanto figures

RR Soybean	1997	—	1.4 million hectares, Argentina 3.6 million hectares, USA
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1998 — 10 million+ hectares (30 per cent) in USA

Yieldguard corn 4 million hectares (12 per cent USA)

China

Transgenic Tobacco first planted in 1992, still shows good viral resistance in the field after 6-7 generations.

1995 30,000 hectares plants
30,000 hectares microorganisms (N₂ fixation)

Recent data on size of planting difficult—no central office for collecting data.

1997 was first year when applications had to be made for *prior* approval for commercialisation/large-scale release.

Approval for commercialisation

Tomato	—	antisense CMV
Sweet pepper	—	CMV
Petunia		
Cotton	—	Bt toxin (Chinese) Bt (Monsanto)
Carp	—	growth hormone
Microorganisms (2)	—	N ₂ fixation

86 applications for release were submitted in 1998, 70 approved for field release/commercialisation.

China

Field release	Small-scale releases
Tobacco	Rice
Cotton	Wheat
Potato	Maize
Soybean	Maize
Tomato	Orange
Sweet Pepper	Agastache rugosa
Poplar (Bt)	Eucalyptus

FDF’s **foodfuture** programme, launched in 1995, aims to improve public understanding of modern food biotechnology. **Foodfuture** has initiated wider discussion of the technology—the perceived benefits and the concerns. **Foodfuture** provides information and develops dialogue with key opinion forming groups. **Foodfuture** involves a range of activities:

PUBLICATIONS

A series of booklets and fact sheets explain, objectively, the technology and its applications. The **foodfuture** interactive disk has been received by all secondary schools.

WEBSITE

The **foodfuture** website has received almost a million visits since its launch in 1997.

MEDIA PROGRAMME

Foodfuture adopts a proactive approach to media relations, targeting all sectors of the UK media aiming to promote media debate and ensure that issues are handled objectively.

ADVERTORIALS

Foodfuture advertorials are published in national and community based publications to raise awareness of the issues. Examples include *Daily Mail* and *BBC Good Food Magazine*.

EXHIBITIONS AND ROADSHOWS

The Science Museum *Future Foods?* Exhibition is supported by FDF, MAFF and BBSRC. Launched by the Ministers for Public Health and Food Safety, it is currently on tour around the UK visiting large visitor centres.

In addition, **foodfuture** messages and materials are distributed direct to the public via a national roadshow visiting 23 major retail centres this year.

FOODFUTURE QUESTION TIME DEBATES

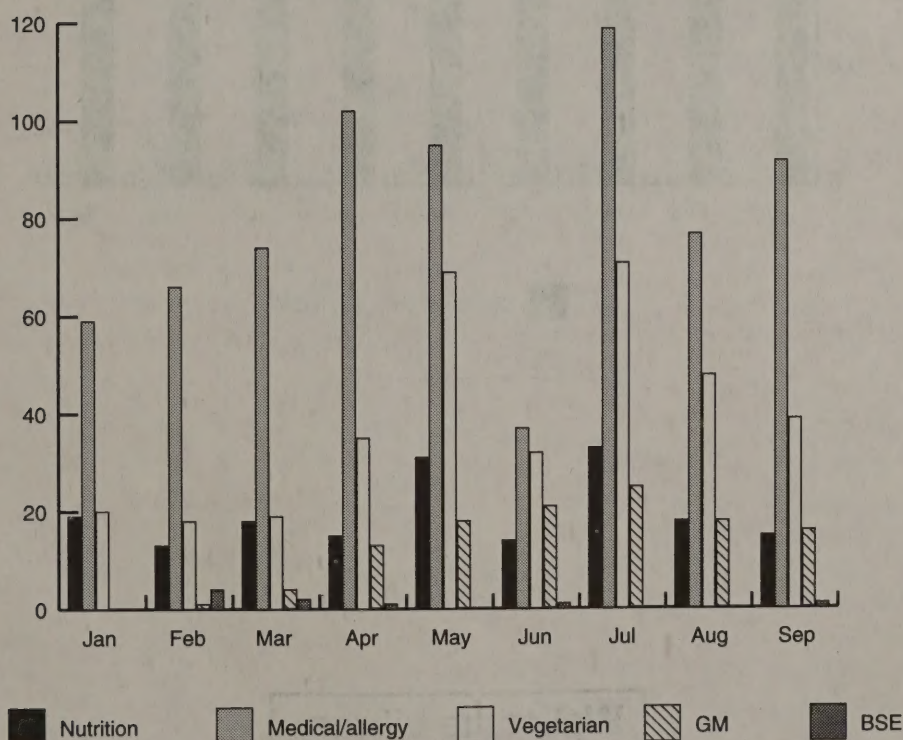
Foodfuture is conducting a series of regional discussion forums, following the Question Time format. The general public are invited to quiz a panel of experts representing all sides of the biotechnology debate. These events have been endorsed by both Jeff Rooker MP, Minister for Food Safety and by John Battle MP, Minister of State DTI.

Audience Feedback:

Sixty-six per cent of those responding to the audience evaluation questionnaire felt the event was *useful to extremely useful* in helping them find out more about GM and 75 per cent reported they would recommend similar events to their friends/family.

Consumer comments

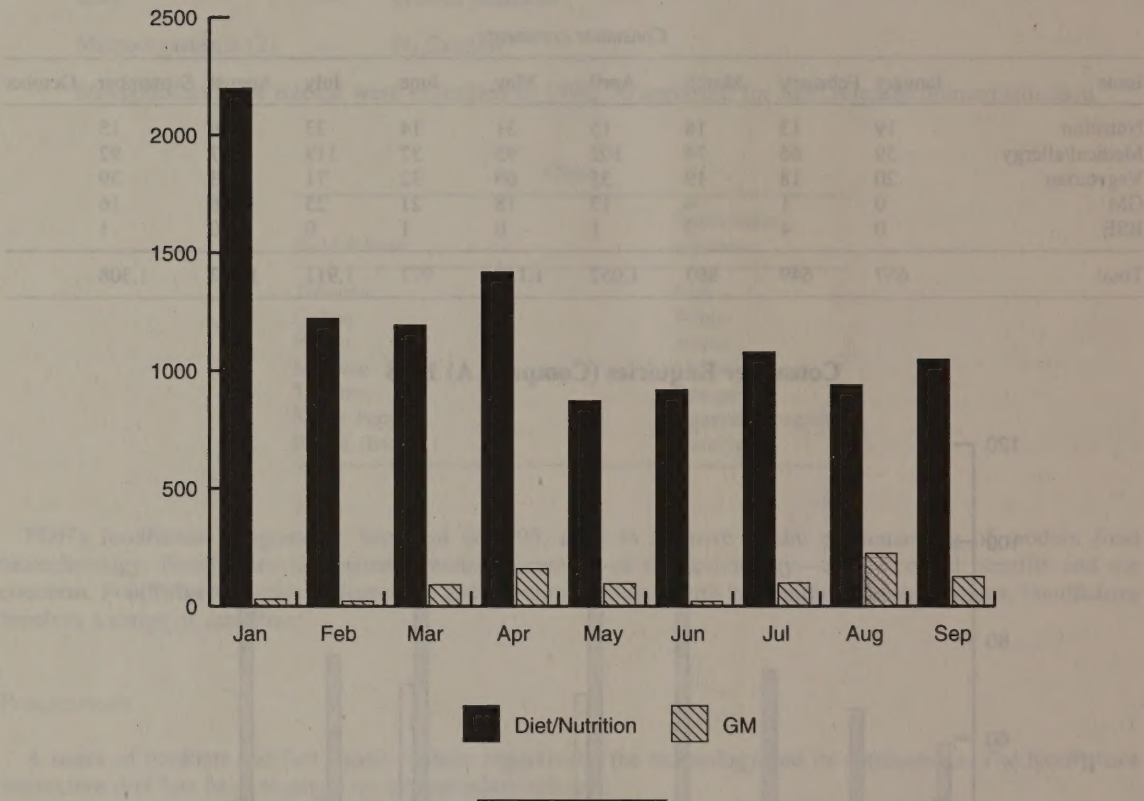
Issue	January	February	March	April	May	June	July	August	September	October
Nutrition	19	13	18	15	31	14	33	16	15	
Medical/allergy	59	66	74	102	95	37	119	77	92	
Vegetarian	20	18	19	35	69	32	71	48	39	
GM	0	1	4	13	18	21	25	18	16	
BSE	0	4	2	1	0	1	0	0	1	
Total	657	649	803	1,052	1,118	977	1,911	1,212	1,308	

Consumer Enquiries (Company A) 1998

Consumer comments

Issue	January	February	March	April	May	June	July	August	September	October
Diet/Nutrition	2,198	1,221	1,193	1,418	871	918	1,076	939	1,048	
GM	30	21	91	159	95	20	98	224	125	
Total	7,352	5,022	4,716	5,756	5,268	4,561	5,639	4,124	5,015	

Consumer Enquiries (Company B) 1998



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